A Global Commitment to Lifelong Protection through Immunization









IMMUNIZATION

PROGRAM

ANNUAL REPORT







NATIONAL IMMUNIZATION PROGRAM 2006 ANNUAL REPORT

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FROM THE DIRECTOR, DR. ANNE SCHUCHAT

The progress achieved through immunization in 2005 in the United States and around the world fills me with admiration for the people, partners, and programs that made this happen. I am thrilled and humbled at the opportunity to lead the National Immunization Program, where on a daily basis, in every time zone, we are improving the health of people, protecting communities, and reducing the disparities in health that affect vulnerable and neglected parts of our society.

In the United States, more infants and toddlers are being protected through immunization against an increased number of diseases. New recommendations for adolescent immunization offer the potential to reduce pertussis and meningococcal meningitis and strengthen the platform for adolescent health promotion. Immunization has interrupted endemic transmission of rubella, and uptake of newer vaccines has resulted in record lows of varicella, pneumococcal disease, and hepatitis A. Increased attention to influenza control provides the opportunity to dramatically improve immunization efforts in adults.

In 2005, unprecedented devastation and challenges to health resulted from nature: the tsunami in South Asia, Hurricane Katrina in the Gulf Coast region, and a massive earthquake in Pakistan. Immunizations are a critical tool in these circumstances, and NIP staff provided assistance to the emergency relief measures, through vaccine recommendations and distribution, and provision of communications, epidemiologic, and emergency response expertise to state and local public health officials. In the United States, immunization information systems provided precious data for children who were displaced from Louisiana, Alabama, and Mississippi, reducing the need for costly revaccination as families relocated.

Preparedness for pandemic influenza also drew the world's attention in 2005. NIP played a critical role in preparedness—from helping to develop the HHS pandemic influenza plan to conducting an innovative public engagement project that sought the public's input on community values for prioritizing vaccine use in the pandemic setting.

The global reach of vaccine-induced prevention also achieved new milestones. Fifty years after the first polio vaccine, NIP continued working with partners on global eradication of polio while also championing measles mortality reduction and strengthening routine immunization activities. This work is reducing illness and death caused by vaccine-preventable diseases, and building the foundation for the introduction of new vaccines in the developing world.

I have quickly learned that the people behind these accomplishments are passionate about their work and truly committed to making a difference to the communities we serve in the United States and worldwide. Through advances in research, technology, and the growth in public and private partnerships and commitment, the future holds awesome possibilities for protecting health through immunization. I thank you for your dedication and hard work and look forward to joining you in "delivering on the possible" in the years ahead.

Sincerely,

Anne Schuchat, MD, CAPT, USPHS

Dr. Anne Schuchat, Director of the National Immunization Program (NIP), Centers for Disease Control and Prevention (CDC), joined CDC in 1988 as an Epidemic Intelligence Service (EIS) officer in the Meningitis and Special Pathogens Branch within the Division of Bacterial and Mycotic Diseases at the National Center for Infectious Diseases (NCID). She served as the first medical director of the Active Bacterial Core surveillance (ABCs)/Emerging Infections Program Network, a multi-state collaboration between CDC, state health departments and academic institutions. Dr. Schuchat became Chief of the Respiratory Diseases Branch (DBMD) in 1998 where she remained through January 2005. From February–November 2005, she served as Acting Director of NCID before beginning her tenure as Director of NIP in December.

During her time at CDC, Dr. Schuchat joined colleagues agency wide on numerous emergency response activities, including the 2001 anthrax bioterrorism response and the 2003 SARS outbreak, where she headed the Beijing City epidemiology team for the WHO China Office. She continues to serve as a visiting professor for the Beijing Centers for Disease Prevention and Control.

Dr. Schuchat has made crucial contributions to the prevention of infectious diseases in children. She is best known for her role in group B streptococcal disease prevention in carrying out epidemiologic studies and surveillance and in spearheading national guidelines for prevention using intrapartum antimicrobial prophylaxis. Based on her work, CDC's guidelines, issued in partnership with the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, have led to an 80% reduction in newborn infections and a 75% narrowing of racial disparity in this infectious disease.

Dr. Schuchat also has played important roles in pre- and post-licensure evaluations of conjugate vaccines for bacterial meningitis and pneumonia. Through ABCs, her work provided the evidence base for the U.S. policy supporting the introduction of pneumococcal and meningococcal conjugate vaccines into routine childhood schedules. The ABCs also documented the impact on bacterial meningitis, invasive disease, and antimicrobial resistance of introductions of these vaccines, as well as the tremendous indirect benefits that the pneumococcal conjugate vaccine used in young children has had on reducing disease in unvaccinated adults and children through interruption of transmission. Dr. Schuchat has assisted in accelerating the availability of new vaccines for the prevention of meningitis and pneumonia in resource-poor countries through consultancies with the World Health Organization and participation in the Global Alliance for Vaccines and Immunization's Hib Initiative.

Her efforts have been recognized with the U.S. Public Health Service (PHS) Meritorious Service Medal, the American Public Health Association's Maternal and Child Health Young Investigator Award, the PHS Physician Research Officer of the Year, and an Honorary Doctorate in Science from Swarthmore College. Dr. Schuchat has published more than 150 articles, chapters, and reviews. She has mentored dozens of Epidemic Intelligence Service officers and others at CDC, and has worked closely with WHO, FDA, NIH, USAID, and IDSA on a number of infectious disease, vaccine, and prevention issues. Dr. Schuchat graduated with Highest Honors from Swarthmore College and with Honors from Dartmouth Medical School. She served as resident and chief resident in Internal Medicine at New York University's Manhattan VA Hospital before beginning her public health career at the CDC.

ANNE SCHUCHAT, MD

CAPTAIN, USPHS

DIRECTOR. NIP



An influential force in extraordinary

STEPHEN L. COCHI, MD, MPH

CAPTAIN, USPHS

ACT. DIRECTOR, NIP 2003-05

DR. STEPHEN L. COCHI, former Acting Director, National Immunization Program, CDC, has been in the forefront of shaping national and international policy, scientific recommendations and funding for control of vaccine-preventable diseases for more than two decades. Dr. Cochi has been a leader in developing national, global and regional immunization initiatives, identifying funding and partners to help achieve immunization objectives, and nurturing these initiatives with a combination of scientific and programmatic expertise. As a result of Dr. Cochi's efforts, millions of children live healthier lives, millions of deaths have been prevented, and the successful immunization initiatives he has led have resulted in a broad range of new public health partnerships to protect the health of children in the United States and around the world.

After medical and postgraduate training at Duke University and CDC, Dr. Cochi served as the Chief of the Infant Immunization Section at CDC and quickly became a recognized expert in the broad range of vaccine-preventable diseases in the United States. Dr. Cochi has published more than 200 journal articles, book chapters, and other articles on polio, rubella, mumps, measles, and other vaccine-preventable diseases.

From 1993 to 2003, Dr. Cochi directed CDC's expanding global immunization activities, a time of unprecedented growth and success in global immunization programs. Dr. Cochi served as a scientific advisor on numerous advisory bodies and helped foster successful partnerships with national and international organizations and governments to make the vision of a more fully vaccinated world a reality. In collaboration with WHO, PAHO, Rotary International, UNICEF, American Red Cross, United Nations Foundation, and other partners, Dr. Cochi's leadership has led to extraordinary achievements.

Dr. Cochi's leadership of the National Immunization Program has been associated with a period of record high vaccination coverage in the United States and with record low levels of vaccine-preventable diseases. NIP thanks Dr. Cochi for his scientific and programmatic leadership and contributions to national and global immunization programs.

- Vaccination of more than a billion children with polio vaccine
- The number of polio cases has been reduced from more than 350,000 annually in 1988 to about 2000 cases in 2005, a decline of more than 99%. More than 250,000 lives have been saved and five million cases of childhood paralysis have been prevented through the global polio eradication initiative. In addition, more than one million lives have been saved since 1998 by administering Vitamin A during polio immunization campaigns.
- Measles deaths have been reduced by 60% in Africa since 1999, saving the lives of more than 300,000 children. Endemic measles has been eliminated from the Western Hemisphere. Measles importations from Latin America into the United States have virtually disappeared from 2000 to 2005.
- Regional measles elimination initiatives have been established in the Western Pacific, European and Eastern Mediterranean regions of WHO, and the first regional initiative to eliminate Hepatitis B was established in the Western Pacific Region in 2005.

NATIONAL IMMUNIZATION PROGRAM MISSION & GOALS

In our efforts to carry out our mission and achieve our goals, the National Immunization Program is committed to:

PROMOTING IMMUNIZATION AT EVERY STAGE OF LIFE

PROVIDING LEADERSHIP ON VACCINES & IMMUNIZATION

STRENGTHENING & COMMUNICATING IMMUNIZATION SCIENCE

ESTABLISHING PARTNERSHIPS & FOSTERING COLLABORATION

PROVIDING IMMUNIZATION EDUCATION & INFORMATION

IMPROVING HEALTH IN THE UNITED STATES & WORLD

MISSION

THE MISSION of the National Immunization Program is to prevent disease, disability, and death in children and adults through vaccination. To achieve this mission, we strive to

- prevent disease
- achieve maximum immunization coverage
- establish effective partnerships
- conduct reliable scientific research
- implement effective immunization systems
- ensure vaccine safety
- promote a positive National Immunization Program work environment

FUTURES INITIATIVE

CDC RECENTLY ENGAGED IN A STRATEGIC PLANNING process, the Futures Initiative, to enhance its capacity to protect and improve the health of the American people in the twenty-first century. The Initiative was designed to strengthen and develop the public health workforce and to meet multiple public health challenges, including those resulting from an aging population, global threats of disease and terrorism, obesity, and epidemic threats of chronic diseases.

To achieve improved health impact, greater agency-wide coordination, better business accountability, and more robust public health research, CDC has developed a set of agency-wide health promotion and preparedness goals and has established Coordinating Centers that identify areas of synergy across CDC's organizational units. The National Immunization Program, the National Center for Infectious Disease, and the National Center for HIV, STD, and TB Prevention comprise the Coordinating Center for Infectious Diseases.

NIP's efforts are helping CDC achieve its two overarching health protection goals that were developed as a result of the Futures Initiative:

- Health promotion and prevention of disease, injury, and disability: All people, especially those at higher risk due to health disparities, will achieve their optimal life span with the best possible quality of health in every stage of life.
- Preparedness: People in all communities will be protected from infectious, occupational, environmental, and terrorist threats.





NIP's work is also consistent with the six strategic imperatives CDC has adopted:

- Achieving measurable health impact
- Being a customer-centric organization
- Strengthening our science through public health research
- Providing leadership in the nation's health system
- Establishing global health priorities
- Becoming more effective and accountable

Within these frameworks, NIP remains committed to achieving the following goals:

- Reducing the number of indigenous cases of vaccine-preventable diseases
- Ensuring that children and adolescents are appropriately vaccinated
- Increasing the proportion of adults and high risk persons who are vaccinated annually against influenza and vaccinated against pneumococcal disease
- Helping domestic and international partners achieve the World Health Organization's goal of global polio eradication
- Working with global partners to reduce the global measles-related mortality
- Improving vaccination coverage estimates by working with providers and promoting the continued use and expansion of immunization information systems

The Government Performance and Results Act (GPRA) and Healthy People 2010 are two goal-planning and performance-measurement processes by which progress toward immunization goals is measured. To learn more about NIP's progress toward reaching domestic and global immunization goals, visit the GPRA website, www.cdc.gov/od/perfplan/2004/2004perf.pdf, and the Healthy People 2010 website, www.healthypeople.gov/document.

1923-1927

Diphtheria, whole-cell pertussis, and tetanus vaccines become available

1963

Measles vaccine licensed

Congress establishes the **Immunization Grants Program** to ensure that children, adolescents, and adults receive appropriate immunizations through partnerships with health providers in public and private sectors

1966

CDC announces the first national Measles Eradication Campaign

1977

Last case in the world of endemic smallpox reported CDC launches National Childhood Immunization Initiative to attain 90% immunization levels in the United States









Advisory
Committee on
Immunization
Practices (ACIP),
designed to
provide CDC
with recommendations about
vaccine use,
holds its first
meeting at CDC



1955

Inactivated polio vaccine licensed

1979

Last case in the United States of polio caused by wild polio virus

IMMUNIZATION'S HISTORY OF SUCCESS

CDC recommends discontinuation of routine vaccination for smallpox in the United States

1971

1991

CDC partners in planning a national immunization initiative to ensure 90% of children are fully immunized by age 2 years CDC provides laboratory support to eradicate polio in the Americas

1995

Chickenpox (varicella) vaccine licensed

2000

Measles no longer endemic in the United **States** Pneumococcal

conjugate vaccine licensed

2003

National Immunization Program celebrates tenth year of record reductions in the United States in vaccinepreventable diseases





1993

National

analysis influences Medicare to cover influenza vaccination

Immunization Program 1988 established to **CDC** establishes increase unit dedicated to immunization global polio coverage and to eradication and protect children provides under age 2 assistance to the from vaccine-World Health preventable Organization in diseases this cause NIP's cost-benefit

1998

Nationwide immunization objectives for 2010 established, including one addressing vaccine safety





Rubella no

longer endemic in the United States NIP's Global **Immunization** Division reports 39% drop in measles-related deaths worldwide between 1999 and 2003

2005

After nearly four decades of vaccinations, CDC announced the elimination of the rubella virus in the **United States**

Lifelong Immunization CHILDHOOD

PROMOTING IMMUNIZATION THROUGHOUT CHILDHOOD

CHILDHOOD IMMUNIZATION SCHEDULE

ONE OF NIP'S MOST IMPORTANT ACTIVITIES is the development and distribution of the childhood immunization schedule, which summarizes recommendations for childhood vaccines in table format. Three advisory bodies collaborate to issue a single schedule of routine childhood immunizations: the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The schedule is continually evaluated to ensure the highest level of effectiveness, efficiency, and safety in childhood immunizations. (See the 2006 Recommended Childhood Immunization Schedule on page 11 and the 2006 Catch-up Tables on page 12.)

VACCINES FOR CHILDREN PROGRAM

CONGRESS ESTABLISHED the Vaccines for Children Program (VFC) in 1993 to better ensure equal access to immunizations for all children. The VFC program is a state-operated federal entitlement program that removes vaccine cost as a barrier to immunization for our neediest children. More than \$1.2 billion was spent by the VFC program in fiscal year 2005 to purchase vaccines for eligible children.

Over 44,100 provider sites are enrolled in the VFC program, and 32,292 of these are private provider sites. The VFC program provides public-purchased vaccine to all enrolled providers who agree to vaccinate VFC-eligible children from birth through 18 years of age. These children must be Medicaid-eligible, without health insurance, American Indian, or Alaska Native. In addition, children who have health insurance that does not cover vaccines are eligible for the VFC program if they are served through a federally qualified healthcare center or rural health clinic.

IMMUNIZATION INFORMATION SYSTEMS

STATE, COMMUNITY, AND HEALTHCARE PROVIDER IMMUNIZATION INFORMATION SYSTEMS

Immunization information systems (IIS) or immunization registries are confidential, computerized information systems that record, store, and provide fast access to children's immunization records. Electronic records and computer information systems are important tools to increase and sustain high vaccination coverage, especially among children. Computerized records improve healthcare providers' abilities to

THE NATIONAL
IMMUNIZATION PROGRAM
works with healthcare
providers, public and private
sector partners, and state and
local government agencies to
ensure that childhood
immunizations remain at
high levels. NIP also works
with these partners to foster
awareness of immunization
recommendations and to
increase knowledge about
vaccines.

update records and to share them with other healthcare providers in a practice, community, or state. Data received from 56 immunization program grantees for the 2004 Immunization Registry Annual Report (IRAR) suggest that 48% of children less than 6 years of age with two or more immunizations were participating in an IIS. This represents a 4% increase from 2003 or approximately 1 million more children who participate in an IIS.

RECENT IMMUNIZATION INFORMATION SYSTEM ACHIEVEMENTS

The Healthy People 2010 immunization information system objective is to increase to 95% the proportion of children participating in fully operational, population-based registries. Ten grantees (Alabama, Arizona, Delaware, Michigan, New Mexico, New York City, North Dakota, Oregon, Philadelphia and Wisconsin) met or exceeded the 95% participation objective as of the end of 2004. An additional seven (13%) IIS grantees (Arkansas, Mississippi, Montana, Oklahoma, Missouri, Rhode

RECOMMENDED CHILDHOOD AND ADOLESCENT IMMUNIZATION SCHEDULE* UNITED STATES • 2006

Vaccine ▼ Age ▶	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	24 months	4–6 years	11-12 years	13-14 years	15 years	16-18 years
Hepatitis B¹	НерВ	He	рВ	HepB¹		He	рВ				НерВ	Series		
Diphtheria, Tetanus, Pertussis²			DTaP	DTaP	DTaP		DT	īaP		DTaP	Tdap		Tdap	
Haemophilus influenzae type b³			Hib	Hib	Hib³	Н	ib							
Inactivated Poliovirus			IPV	IPV		IF	V	I		IPV				
Measles, Mumps, Rubella⁴						МІ	VIR			MMR		М	MR	
Varicella ^s							Varicella				Vari	cella		
Meningococcal ⁶							brokei	cines within line are for populations	MP	SV4	MCV4		MCV4	
Pneumococcal ⁷			PCV	PCV	PCV	P	CV		PCV		P	PV		
Influenza ⁸					ı	nfluenza	(Yearly)			Influenza	a (Yearly)	
Hepatitis A°									н	epA Seri	es	1	1	

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2005, for children through age 18 years. Any dose not administered at the recommended age should be administered at any subsequent visit when indicated and feasible.

Indicates age groups that warrant special effort to administer those vaccines not previously administered. Additional vaccines may be licensed and recom-

mended during the year. Licensed combination vaccines may be used whenever

any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective ACIP statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Range of recommended ages Catch-up immunization 11-12 year old assessment

The Childhood and Adolescent Immunization Schedule is approved by:
Advisory Committee on Immunization Practices www.cdc.gov/nip/acip • American Academy of Pediatrics www.aap.org • American Academy of Family Physicians www.aafp.org

^{*} Please see accompanying footnotes in the Annex of this publication. The "Catch-up Schedule" follows on the next page.

RECOMMENDED IMMUNIZATION SCHEDULE* FOR CHILDREN AND ADOLESCENTS WHO START LATE OR WHO ARE MORE THAN 1 MONTH BEHIND

UNITED STATES • 2006

The tables below give catch-up schedules and minimum intervals between doses for children who have delayed immunizations. There is no need to restart a vaccine series regardless of the time that has elapsed between doses. Use the table appropriate for the child's age.

	CATC	H-UP SCHEDULE FOR CH	IILDREN AGED 4 MONTH	IS THROUGH 6 YEARS					
Vaccine	Minimum	Minimum Interval Between Doses							
vaccine	Age for Dose 1	Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5				
Diphtheria, Tetanus, Pertussis	6 weeks	4 weeks	4 weeks	6 months	6 months ¹				
Inactivated Poliovirus	6 weeks	4 weeks	4 weeks	4 weeks²					
Hepatitis B³	Birth	4 weeks	8 weeks (and 16 weeks after first dose)						
Measles, Mumps, Rubella	12 months	4 weeks⁴							
Varicella	12 months								
Haemophilus influenzae type b ^s	6 weeks	4 weeks if first dose given at age <12 months 8 weeks (as final dose) if first dose given at age 12-14 months No further doses needed if first dose given at age ≥15 months	4 weeks ⁶ if current age <12 months 8 weeks (as final dose) ⁶ if current age ≥12 months and second dose given at age <15 months No further doses needed if previous dose given at age ≥15 mo	8 weeks (as final dose) This dose only necessary for children aged 12 months-5 years who received 3 doses before age 12 months					
Pneumococcal ⁷	6 weeks	4 weeks if first dose given at age <12 months and current age <24 months 8 weeks (as final dose) if first dose given at age ≥12 months or current age 24–59 months No further doses needed for healthy children if first dose given at age ≥24 months	4 weeks if current age <12 months 8 weeks (as final dose) if current age ≥12 months No further doses needed for healthy children if previous dose given at age ≥24 months	8 weeks (as final dose) This dose only necessary for children aged 12 months-5 years who received 3 doses before age 12 months	SAFEL HEALTHER PROPER				

CATCH-UP SCHEDULE FOR CHILDREN AGED 7 YEARS THROUGH 18 YEARS								
Vaccine	Minimum Interval Between Doses							
vaccine	Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Booster Dose					
Tetanus, Diphtheria ⁸	4 weeks	6 months	6 months if first dose given at age <12 months and current age <11 years; otherwise 5 years					
Inactivated Poliovirus°	4 weeks	4 weeks	IPV ^{2,9}					
Hepatitis B	4 weeks	8 weeks (and 16 weeks after first dose)						
Measles, Mumps, Rubella	4 weeks							
Varicella¹º	4 weeks							

^{*} Please see accompanying footnotes in the Annex of this publication. The main Childhood and Adolescent Schedule is found on page 11.

Island, and Tennessee) are approaching the national health objective with participation rates of 81%–94%.

Approximately 76% of public vaccination provider sites and 39% of private vaccination provider sites submitted vaccination data to an IIS during the last 6 months of 2004. Twenty-eight (50%) grantees reported that more than 95% of public provider vaccination sites submitted vaccination data to an IIS; five (9%) reported submission of vaccination data by 81%–94% of public provider vaccination sites. Seven (13%) grantees (Arkansas, Connecticut, Mississippi, New Mexico, South Dakota, Philadelphia, and San Antonio) reported that more than 95% of private provider vaccination sites submitted vaccination data to an IIS; eight (14%) (Arizona, Delaware, District of Columbia, Michigan, North Dakota, Oregon, South Carolina, and Wisconsin) reported data submission by 81%–94% of private provider sites.

In 2005, the Immunization Registry Support Branch (IRSB) in coordination with Public Health Informatics Institute (PHII) launched the Enhanced Technical Assistance (ETA) Project. Through the ETA, selected grantees will be provided assistance in identifying the barriers to successful IIS development and implementation, and in developing a plan of action to overcome these barriers. Currently IRSB/PHII is working with its first grantee recipient to develop a business and strategic document that describes the approach and tasks necessary to achieve the successful implementation of an IIS within the scope of their project catchment area. With this document, the grantee will implement measures to ensure their attainment of the Healthy People 2010 registry objective.

The American Immunization Registry Association (AIRA) joined the Health Level 7 (HL7) standards workgroup in 2005. HL7 is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the electronic exchange of clinical, financial, and administrative information among healthcare oriented computer systems. AIRA members actively worked on the development of use cases for immunizations in collaboration with the HL7 pediatric Special Interest Group. AIRA continues to promote the exchange of data between managed care organizations (MCOs) and immunization registries by building the capacity of registries, while Every Child By Two works with individual managed care organizations and with the American Academy of Pediatrics, America's Health Insurance Plans, and the National Committee for Quality Assurance.

To assist grantees in developing a standardized approach to linking their immunization information systems with the Vaccine Adverse Event Reporting System (VAERS), AIRA formed the Vaccine Safety and Registry Community Work Group. Collaborating with CDC, this workgroup used a consensus-based approach to analyze reporting scenarios, functional capacities, and VAERS reporting requirements. The VAERS reporting system is improving its ability to electronically receive data, including the ability to receive standard electronic messages and Webbased reports. For more information about VAERS, see the Leadership in Vaccine Safety section of this report.

CDC continues to fund **immunization information systems sentinel sites** that promote the population-based analysis of IIS data for assessment, surveillance,

and immunization program evaluation. Funds are used by the sites in a variety of ways, including developing data quality improvement initiatives and calculating estimates of immunization coverage levels. These coverage estimates have been used at the national level to monitor the impact of vaccine shortages, most notably during the 2003–04 influenza vaccination season. To continue to expand national IIS activities, NIP invited eligible state registries to apply for funds and develop either a capacity building IIS site, aimed at improving IIS data quality and providing support for routine analysis of IIS data, or an implementation IIS site, aimed at performing numerous statistically-based, population-based assessments among children up to 18 years of age.

To assist grantees in developing standardized operational procedures in the immunization information systems, AIRA, in collaboration with CDC, used a consensus-based approach to develop guidelines on the management of the "Moved or Gone Elsewhere" and other patient immunization status in immunization information systems. It is expected that these guidelines will aid systems in the adoption of common practices for determining patient status, promote consistent use of definitions and rules of operations, thus improving data quality and usefulness of registry information.

Despite the devastation caused by Hurricane Katrina, the immunization information systems in Louisiana (LINKS), Alabama (ImmPRINT), and Mississippi (MS Immunization Registry) remained operational, and grantee IIS staff worked hard to ensure stability and accessibility for other grantees needing immunization histories for displaced children. Schools or health agencies outside of the three Hurricane Katrina-impacted states needing immunization histories for displaced children contacted their state or local immunization information system for assistance in accessing records. Virtually all grantees were given access to LINKS, where the Immunization Registry Annual Report data suggested that 79% of children aged 0–6 (289,438 of 365,874) had at least two immunizations recorded in the system.

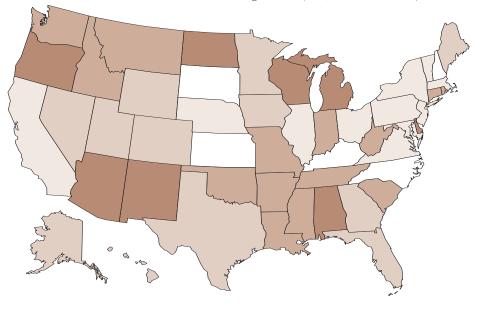
in the United States who are Between 4 Months and 6 Years of Age and have at Least Two Immunizations Registered in an Immunization Information System (IIS) as of December 31, 2004.

PERCENTAGE of CHILDREN

Source: Immunization Registry Annual Report, CY2004

No Report

0-33%



As a result, more than 20,000 immunization histories for displaced children were accessed, thereby reducing or eliminating the need for re-vaccination to be in compliance with school immunization laws.

Benefits of Immunization Information Systems

For **parents**, IISs provide many benefits, including

- Consolidation of immunization histories for individual children
- An accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements
- Ensuring that a child's immunizations are up to date

34–66%

67-94%

95-100%

- Reminders when vaccination is due
- Recall notices when vaccination has been missed
- Timely immunization for children whose families move or switch healthcare providers
- Prevention of unnecessary (redundant) immunization

For healthcare providers, IISs offer many advantages, including

- Consolidation of immunizations from all providers
- A reliable immunization history for any child, whether a new or continuing patient
- Definitive information on immunizations which are due or overdue
- Current recommendations and information on new vaccines
- Reminder and recall notices for patients

For public health officials, IISs offer

- Information to identify pockets of need, target interventions and resources, and evaluate programs
- Promotion of reminder and recall of children who need immunizations
- Assurance that providers will follow the most up-to-date recommendations for immunization practice
- Assistance with the introduction of new vaccines or changes in the vaccine schedule
- Integration of immunization services with other public health functions
- Help to monitor adverse events

Continuing Efforts for Immunization Information Systems

To reach the Healthy People 2010 objective of 95% of children participating in population-based systems and to support NIP's mission to prevent disease, disability, and death in children and adults through vaccination, the goal of immunization information systems is to generate data to support clinical decision-making by providers and to support immunization program efforts to provide strong leadership, sound decisions, effective priorities, and strong program accountability. To achieve this goal, NIP has developed plans to

- Improve grantee accountability for funding received from NIP for the development and implementation of immunization information systems
- Review procedures used to assess grantee progress and challenges in implementing IISs
- Develop an IIS Evaluation and Research agenda to promote IISs by conducting evaluation and research studies
- Develop and implement an objective evaluation or measure of IIS functionality achievement through a certification or other process
- Advance the IIS interoperability with the national initiative to develop electronic medical records and electronic health records
- Advance national strategies to use IIS data
- Support and maintain a focus for IIS at CDC

THE NATIONAL IMMUNIZATION SURVEY

THE NATIONAL IMMUNIZATION SURVEY (NIS) is the nation's primary tool for assessing immunization coverage among preschool-aged children in the United States. This random-digit-dial telephone survey is conducted annually by CDC to obtain national, state, and selected urban-area estimates of vaccination coverage rates for U.S. children aged 19–35 months. Vaccination information obtained from the telephone survey is then validated by surveys that are mailed to the children's vaccination providers.

NIS data revealed that in 2004 coverage with 4 or more doses of any diphtheria and tetanus toxoids and pertussis vaccine (DTP/DTaP/DT) was 85.5%, coverage with 3 or more doses of any poliovirus vaccine was 91.6%, coverage with 1 or more doses of measles-mumps-rubella vaccine (MMR) was 93.0%, coverage with 3 or more doses of Hib vaccine was 93.5%, and coverage with 3 or more doses of hepatitis B vaccine was 92.4%.

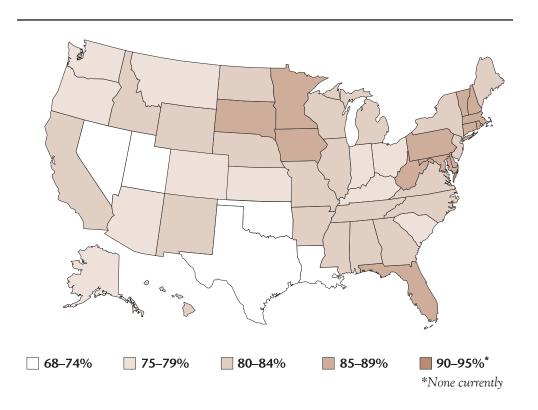
For the first time, vaccination coverage (80.9%) for the 4:3:1:3:3 series exceeded the *Healthy People 2010* goal (*objective 14-24a*) to increase to at least 80% the proportion of children aged 19-35 months who receive all vaccines recommended for universal administration for at least 5 years.

ESTIMATED VACCINATION COVERAGE of U.S. CHILDREN 19-35 Months of Age with 4:3:1:3:3

- four or more doses of DTaP
- three or more doses of poliovirus vaccine
- one or more doses of any measlescontaining vaccine
- three or more doses of Hib, and
- three or more doses of HepB

National Average: 80.9% (±0.9%) Exceeds the Healthy People 2010 goal to increase to at least 80% the number of children receiving all vaccines recommended for universal administration.

Source: National Immunization Survey, 2004



Furthermore, coverage with one or more doses of varicella vaccine at or after the child's first birthday (unadjusted for history of varicella illness) increased from 67.8% in 2000 to 87.5% in 2004. Estimates of vaccination coverage for children aged 19–35 months based on NIS data can be found on the NIP website at www.cdc.gov/nip/coverage; estimates are reported there for years 1995–2004 and can be viewed by state, by certain urban reporting areas, and by demographic characteristics.

A study published in 2005 examined the variability among states in timeliness of vaccination among children aged 24 to 35 months; usually, vaccination coverage measures examine the number of vaccinations received by a certain age. The authors analyzed data from the 2000–2002 NIS and found that receipt of all vaccinations as recommended ranged among states from 2% to 26%. They concluded that children rarely receive all vaccinations as recommended. They suggest that state health departments use timeliness of vaccination along with other measures to determine children's susceptibility to vaccine-preventable diseases and to evaluate the quality of vaccination programs.*

The NIS also now collects children's entire provider-reported, influenza-vaccination histories. Beginning in 2002, ACIP encouraged annual influenza vaccination, when feasible, for all children aged 6–23 months and their household contacts, and for out-of-home caregivers for children aged less than 2 years. For the 2004-2005 influenza season, ACIP recommended vaccination for these groups.

NIS data indicate that 18% of children aged 6–23 months during the influenza season received one or more influenza vaccinations in the 2003-04 influenza season (the second year of the ACIP encouragement), and 8% of children in the age group were fully vaccinated against influenza. To be fully vaccinated, these children receive two doses if not previously vaccinated or one dose if previously vaccinated against influenza. Overall, substantial variability in influenza coverage was observed among states and selected urban reporting areas.

Rotation of the Immunization Action Plan (IAP) areas on the NIS was implemented in 2005 to allow for the assessment of immunization coverage in new areas with potentially low coverage. Five original IAP urban areas were not targeted for sampling by the NIS in 2005. A National Association of City and County Health Officials (NACCHO) Task Force developed recommendations for five new areas to be sampled, and five original urban IAP areas with stable, high vaccine coverage not to be targeted for sampling. Vaccine coverage estimates will be available every other year for new areas added to the NIS and for the original urban IAP areas chosen for rotation. The new areas added for 2005 included the California counties of Alameda and San Bernardino; a Denver, Colorado, tri-county area; St. Louis City and County, Missouri; and Clark County, Nevada. Original urban IAP areas chosen for rotation in 2005 included Santa Clara County and San Diego County, California; Miami-Dade County, Florida; Marion County, Indiana; and Boston, Massachusetts.

^{*}American Journal of Public Health. 2005;95: 1367-1374)





SCHOOL AND CHILDCARE VACCINATION SURVEYS

State laws require that children be immunized if they attend a childcare facility and when they enter school. Immunization records of children entering school are reviewed each fall. In addition, states conduct studies to validate reports from schools. Results from these studies are used to ensure high vaccination levels in the population of children enrolled in schools. Periodic assessments also are conducted in childcare facilities. A summary of the coverage results of children in schools, childcare centers, and Head Start programs and of state laws about vaccination is reported annually to the NIP. The most recent survey results can be viewed on the CDC-NIP website at www.cdc.gov/nip/coverage/schoolsurv/overview.htm.

IMPROVING IMMUNIZATION RATES

ASSESSMENTS OF PROGRESS

AFIX: Assessing Immunization Levels and Improving Immunization Rates at Provider Practices

Researchers at NIP led efforts to validate and promote a quality improvement strategy, AFIX (Assessment, Feedback, Incentives, Exchange), that is now recommended nationwide as a standard of practice. The AFIX strategy helps public and private immunization providers determine practice coverage levels and implement programs to improve immunization rates. AFIX uses assessment and feedback about immunization levels to move the practice toward a standard of excellence. NIP research demonstrated that this strategy, which originated in a Georgia immunization program, could be successfully applied nationwide. Healthy People 2010 includes the objective that 90% of all immunization providers receive an assessment and feedback in the past two years. NIP staff are currently researching the most cost-effective methods for conducting assessment and feedback at the more than 40,000 provider sites that use federally purchased vaccine.

AFIX and VFC

AFIX has been applied through the Vaccines for Children (VFC) program to improve immunization coverage levels among preschool children. During the last decade, the VFC program has enabled low income, underinsured, uninsured, and other eligible children to receive immunizations in a "medical home" (from a consistent provider at a single site) rather than being referred to the local health department for immunization. Because many VFC participants receive immunizations from private healthcare providers, CDC initiated the VFC-AFIX project to promote AFIX to private provider sites participating in the VFC program. The year 2005 marked the fifth full year that all eligible NIP grantees participated in this initiative. NIP also offers its grantees written guidelines and technical assistance for implementing an AFIX program.

Comprehensive Clinic Assessment Software Application

The Comprehensive Clinic Assessment Software Application (CoCASA) is a software tool used to assess immunization coverage in healthcare settings where immunizations are delivered. CoCASA can provide diagnostic information about

immunization administration practices. The application generates diagnostic reports that identify late starts and missed opportunities for simultaneous vaccine administration, as well as children that are due or overdue for immunizations. CoCASA can assess immunization coverage for children, adolescents and adults. Because CoCASA was developed by CDC, the software is public domain and can be installed and shared with others at no cost.

IMPROVING IMMUNIZATION AMONG DISADVANTAGED CHILDREN

WOMEN, INFANTS, AND CHILDREN PROGRAM

Researchers at NIP conducted a pioneer study of the effectiveness of a partnership between immunization providers and clinics that operate through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). WIC serves 45% of infants nationwide and more than five million children under the age of five. WIC is also the single largest point of access to health services for low-income preschool children who are at the highest risk for low vaccination coverage. A White House Executive Memorandum, dated December 11, 2000, directed WIC clinics to assess the complete immunization status of their clients, a complex task given the nearly two dozen required doses of recommended vaccines. Because many clinics did not have the resources to carry out a complete assessment, NIP researchers developed and validated a simpler alternative, assessing coverage for a single vaccine —DTaP—as a proxy for assessing the complete vaccination record. This assessment method went into effect in late 2002 and has resulted in an increase in the number of WIC clinics nationwide that offer immunization assessment and referral as part of standard operating procedures.

REDUCING DISPARITIES AMONG RACIAL AND ETHNIC POPULATIONS

Eliminating health disparities among racial and ethnic populations in the United States is a major public health goal. However, in recent years, disparities in immunization rates between black and white children have been increasing, especially in certain areas. Therefore, NIP is supporting projects that may lead to reductions in these disparities. Beginning in late 2005, NIP began funding two projects aimed at reducing racial and ethnic disparities in childhood immunization. The purpose of these community-based demonstration projects is to identify, implement and evaluate interventions that will result in a statistically significant reduction in racial disparities in immunization coverage levels between black children 19–35 months of age and children of other races. These interventions include both enhancement of healthcare utilization and strategies to reduce missed opportunities for immunization.

IMPROVING VACCINE MANAGEMENT AND DELIVERY

NIP distributes over 60 million doses of pediatric vaccine every year, almost 60% of the pediatric vaccine used in the United States. The bulk of this vaccine is distributed





through the Vaccines for Children program. VFC has been a recognized success, consistently increasing provider enrollment, improving access for eligible children, and improving national immunization levels. However, many vaccine management and accountability processes are still conducted in ways established more than a decade ago.

VACCINE MANAGEMENT BUSINESS IMPROVEMENT PROJECT

In late 2003, NIP was challenged by HHS and by the President's Management Agenda to improve its business practices. New requirements, such as implementing a national pediatric stockpile and eliminating non-compliant funding practices, compelled NIP to re-examine the operating model for vaccine programs. Due to the complexity of the existing vaccine supply system, HHS, CDC, and the Government Accountability Office (GAO) also requested an analysis of the current system. Most methods and processes used to manage vaccines are derived from models put into place with the inception of the VFC program 10 years ago, and some processes were first used as early as the 1960s. These processes include stand-alone computer applications, offline spreadsheets, and paper-based, manually updated records. No uniform process to manage and track supplies is available, and no electronic or automated system supports or oversees the distribution, supply, and availability of vaccines. Yet over the past decade, the number of children served and the number of doses of vaccine provided have increased dramatically. In addition, several vaccines have been added to the list of recommended childhood vaccines. The processes that were adequate to manage and serve participants in 1994 are not sufficient for the public health needs of the twenty-first century. As a result of these requirements and concerns, the Vaccine Management Business Improvement Project (VMBIP) was initiated.

VMBIP is intended to simplify processes for ordering, distributing, and managing vaccines. The program will improve responses to public health crises related to disease outbreaks, vaccine shortages, and disruption of the vaccine supply. A more efficient vaccine supply system will, in turn, result in the redirection of public health resources from vaccine distribution to other critical public health activities which have improved immunization coverage. The project will also improve the accountability of the VFC program. Finally, the project will significantly reduce the lead time between orders for and delivery of vaccine and will enable the direct delivery of vaccines to providers.

NIP gathered a team to analyze the systems for managing and distributing vaccines and recommend improvements to them. This team spent the early part of 2004 examining the entire vaccine supply chain, from manufacturers to providers. In addition to working with CDC headquarters staff in Atlanta, the team visited ten state and local immunization projects, four vaccine manufacturers, and two vaccine distributors. The team studied many aspects of the VFC program, including funds management, vaccine distribution, provider ordering, inventory management, and the operation of the national pediatric stockpile.

In April 2004, the VMBIP team presented its findings to CDC and NIP leadership. A much more consolidated approach to vaccine ordering and distribution was

recommended. This new model departs from the current fragmented, decentralized approach and shows, at any time, where the product is in the supply chain information essential to improving the nation's vaccine supply. The VMBIP team developed a detailed description of the components of a robust vaccine management program. The team has engaged over 70 staff members from federal and state immunization programs and set up workgroups for all major aspects of the program, including Ordering and Distribution, Vaccine Stockpile, Systems, Fiscal Operations, Vaccine Management and Accountability, and Communications. The workgroups have identified requirements for the new program model and drafted a request for proposals for distribution services.

Throughout this period of investigation, the team collaborated with many groups involved in vaccine programs, including leadership within NIP, CDC, HHS, and the National Vaccine Program Office (NVPO), partner organizations such as the Association of Immunization Managers (AIM), the Association of State and Territorial Health Officials (ASTHO), Every Child by Two, the National Association of County and City Health Officials (NACCHO), the American Immunization Registry Association (AIRA), and immunization program managers. The team has been encouraged by the positive feedback and the constructive suggestions received thus far and will continue to work closely with all vaccine program stakeholders.

The VMBIP team recently accomplished a key milestone with transition to a different methodology for obligating vaccine funding. Vaccine funds are now obligated against manufacturer contracts, enabling CDC to better match vaccine funds with grantee needs. In addition, a request for proposal for centralized distribution was released and a contract award is anticipated in the spring of 2006. Planning continues for the piloting of the centralized distribution process, scheduled to begin in mid-2006, involving several grantee states and urban cities. When the pilot programs have been validated, the new system will be rolled out nationwide, beginning with those that already use commercial distributors, then moving to those states that now distribute vaccine through state-sponsored systems. By late 2008, it is anticipated all 64 grantees will have transitioned to the new centralized distribution model.

NEW VACCINE SURVEILLANCE NETWORK

The New Vaccine Surveillance Network (NVSN), established in 1999, assesses the impact of new vaccines and new vaccine policies on children who are hospitalized or seen in emergency departments or outpatient settings in Rochester, New York; Nashville, Tennessee; and Cincinnati, Ohio. Highlights of work conducted during 2005 include a study focused on

- Estimating the effectiveness of influenza vaccine in preventing laboratoryconfirmed influenza hospitalizations among children under 5 years of age
- Assessment of the benefit of maternal influenza vaccination in protecting infants less than 6 months of age who are too young to receive influenza vaccine
- Surveillance for pertussis disease among children less than 6 months of age
- Assessment of the impact of pneumococcal conjugate vaccine on otitis media, and pneumonia



Oftentimes, information gained from these studies is used to in the development of new vaccine recommendations for the United States. For example, through data collected and analyzed by the NVSN, NIP learned that a high rate of hospitalizations, emergency room visits, and doctors' office visits were associated with influenza in young children. NIP also learned that influenza vaccine helped prevent laboratory-diagnosed influenza during the 2003-2004 influenza season. This information was important in establishing the recent ACIP recommendation to vaccinate children 6 to 23 months of age routinely.

In response to the February 2006 licensure of the new rotavirus vaccine (RotaTeq®), the NVSN will conduct rotavirus surveillance in the upcoming season to estimate baseline disease burden among children under 3 years of age in hospital, emergency department and outpatient practice settings in the sites' counties. Surveillance data will provide important information for monitoring post licensure rotavirus vaccine performance and impact of the vaccine program on rotavirus disease.



Vaccine University

In 2005, NIP convened its first Vaccine University November 30 in Atlanta, Georgia. Three hundred and twenty-five participants registered for the two-and-a-half-day training, representing over 90% of the immunization programs.

This vaccine training program was developed specifically for Immunization Program grantee staff members who provide daily oversight to the Vaccines for Children (VFC), Vaccine Management, and AFIX immunization programs at the state or local level. Vaccine University was planned by a workgroup within the Immunization Services Division (ISD) at NIP and one member of the Association of Immunization Program Managers (AIM). Educational tracks were offered for each of the VFC, Vaccine Management, and AFIX programs.

Presentation highlights from the Vaccine University training included:

- Forecasting vaccine need for 2006 and beyond
- The Top Ten Vaccine Storage and Handling Issues
- Training on the new Comprehensive CASA software in context of the overall AFIX process
- Understanding CDC vaccine contract procurement, management and distribution activities
- Getting the most out of VFC site visits

Of the participants who completed the training evaluation, 98% reported that they "would like to see Vaccine University held again," and 58% thought it should be held on an annual basis. Discussions are underway about future Vaccine University training.



SUCCESS

STORY



SPECIAL

REPORT

VACCINES: PUBLIC HEALTH ECONOMICS

Vaccines have had a profound impact on the health of people around the world from the eradication of smallpox worldwide to the elimination of polio and rubella in the western hemisphere. As one of the most cost-effective interventions in the history of public health, vaccines have been and continue to be responsible for a dramatic reduction in the incidence of numerous lifethreatening diseases. Figures 1 and 2 illustrate the percent reduction in estimated annual cases of vaccine-preventable diseases in the United States from twentieth century pre-vaccine era to the number of cases reported in 2004.

An integral part of achieving this success has been the significant investment of philanthropic and public health organizations, pharmaceutical companies, as well as local and state governments in vaccine development, production and administration. This investment in immunization has led to the highest vaccination coverage rates and lowest rates of vaccine-preventable diseases since the first vaccines were administered.

A vaccine goes through years of research and clinical trials before making it to the public and private market. Even after vaccines have been

associated with their distribution and administration, from cost incurred through federal contracts through the state level where they are distributed to the provider level for administration. Figure 4 outlines the basic steps involved from vaccine research and development to monitoring coverage and distribution.

In 1983, vaccines for seven diseases were available and recommended for routine use in the United States—measles, mumps, rubella, diphtheria, tetanus, pertussis, and polio. In 2005, vaccines for 14 diseases were available and recommended for use. It is projected that

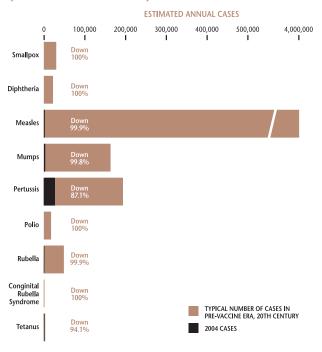
more than 20 vaccines may be available for use in preventing disease by the year 2020. Figure 3 illustrates the increasing numbers of recommended vaccines available and projected within the next 15 years. Accompanying the benefits of these new vaccines will be logistic and economic challenges.

Working with epidemiologists, program consultants, state and local program managers, and academic researchers, NIP economists are addressing a broad range of research topics, including evaluation of the cost-effectiveness and cost-benefit of vaccines and vaccination programs, analysis of vaccine markets and policies, including factors affecting U.S. manufacturers' decisions to produce vaccines, and estimations of illness costs of vaccine-preventable diseases. Research results from NIP's economics team have seen worldwide distribution and use.

An economic evaluation of the seven-vaccine routine immunization series found that it results in billions of dollars of direct cost savings and even greater savings when examined from a societal perspective. A study of varicella vaccine showed cost savings for that vaccine as well and required a novel approach to analysis. NIP economic team staff examined administrative and billing data and determined the impact of the varicella vaccination program on medical visits and associated expenditures. Economists from NIP collaborated with economists and epidemiologists from NCID to provide economic data used by the ACIP in recommending meningococcal conjugate vaccine for adolescents. An analysis of vaccine markets has provided better understanding of how vaccine manufacturers make production decisions and insights into how they price vaccines. These and other activities demonstrate how NIP is leading the way in the development of public health economics research.



Figure 1. COMPARISON OF 20TH CENTURY ESTIMATED ANNUAL CASES AND 2004 REPORTED CASES OF VACCINE-PREVENTABLE DISEASES (PRE-1990 VACCINES)



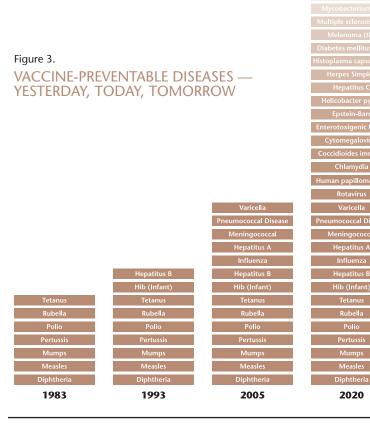


Figure 2. COMPARISON OF PRE-VACCINE ERA ESTIMATED ANNUAL CASES AND 2004 ESTIMATED CASES OF VACCINE-PREVENTABLE DISEASES (POST-1990 VACCINES)

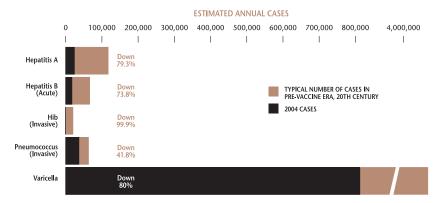


Figure 4. VACCINE — FROM RESEARCH TO MARKET RESEARCH & DEVELOPMENT FDA LICENSURE (monitoring for adverse events) FINANCING UPTAKE & ADMINISTRATION

2020

Lifelong Immunization ADOLESCENCE

PROMOTING ADOLESCENT IMMUNIZATION

New vaccines and vaccine RECOMMENDATIONS for adolescents have recently occurred and more are likely to occur within the next few years. Experience with adolescent vaccine delivery is limited, and developing a system to deliver and finance vaccines to this population is becoming increasingly important.

PRIOR TO 2005, THE ONLY VACCINE ROUTINELY RECOMMENDED for adolescents was the tetanus and diphtheria toxoids (Td) booster. Three other vaccines, hepatitis B, measles-mumps-rubella, and varicella, were indicated as "catch-up" vaccinations for adolescents who were not up to date or, in the case of varicella, lacked vaccination and had negative history of disease.

LICENSURE OF NEW ADOLESCENT VACCINES

IN 2005, THE FDA LICENSED NEW VACCINES to prevent *Neisseria meningitidis* and *Bordetella pertussis*, and the Advisory Committee on Immunization Practices (ACIP) recommended them for routine use in adolescents. The first of the new vaccines was a quadrivalent conjugate vaccine (MCV4) for the prevention of invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y and W-135. Next came two tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) products . Tdap is indicated for booster immunization against tetanus, diphtheria and pertussis. ACIP recommendations for these vaccines have been published in the CDC's *Morbidity and Mortality Weekly Report* (available at www.cdc.gov/nip/publications/acip-list.htm).

MENINGOCOCCAL DISEASE

Over the past few decades, the incidence of invasive meningococcal disease in the United States has ranged from 0.5 to 1.7 cases per 100,000 population (1,400–2,800 cases). The death rate has remained between 10% and 14%; 11% to 19% of survivors suffer serious sequelae, including deafness, neurologic deficit or limb loss. Disease is seasonal, with cases peaking in December and January. Incidence is highest among infants younger than 1 year (9 per 100,000—16% of the total cases). Incidence increases during adolescence, peaking at 2 per 100,000 among 18 year olds. For reasons that are not completely understood, college freshmen living in dormitories also have an increased risk of infection. Transmission occurs when close, face-to-face contact permits the exchange of salivary secretions from people who are ill or carriers. Adolescents and young adults have the highest carriage rates, but few develop disease. However, every case triggers a costly public health response. Due to the effectiveness of antibiotic prophylaxis following confirmed cases, most cases (97%) are sporadic and only a minority (3%) is associated with outbreaks.

MCV4

Worldwide, five serogroups of the bacterium—A, B, C, Y and W-135—cause most disease. In the United States, serogroups B, C and Y cause almost all cases. Two vaccines are available in the United States, the older meningococcal polysaccharide vaccine and the new meningococcal conjugate vaccine, MCV4. Both protect against the A, C, Y and W-135 serogroups but not serogroup B. MCV is created with an antigen that alone induces a suboptimal antibody response (the polysaccharide coating of the bacterium). When bound to a stronger antigen (diphtheria protein), the combination, or conjugate, causes the immune system to recognize the polysaccharides and develop antibodies. Meningococcal conjugate vaccine is therefore expected (but not proven) to have a longer duration of immunity.

PERTUSSIS

Following the introduction of routine childhood immunization against pertussis in the 1940s, the number of reported pertussis cases declined dramatically, reaching an historic low of 1,010 in 1976. Since then, the number of reported cases has been steadily increasing, especially among adolescents and adults. Possible reasons for the increase in reported pertussis cases include a true increase in the burden of disease and an increase in the detection and reporting of cases. Massachusetts has an especially good surveillance system for pertussis and uses an in-state, standardized serology test to confirm cases. During 1996–2004, the average annual incidence of pertussis reported in Massachusetts adolescents aged 11–18 years was 93 per 100,000 population. Adolescents with pertussis commonly experience a prolonged cough and sometimes have complications. In most years, no pertussis-related deaths are reported among adolescents, although they can occur.

Tdap

The pertussis antigen composition of Tdap is similar to pediatric diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) that is administered to infants and young children, but some pertussis antigens are reduced in quantity. The tetanus and diphtheria toxoid composition of Tdap is similar to adult tetanus and diphtheria toxoids vaccine (Td). A single dose of Tdap is routinely recommended, instead of Td, for adolescents aged 11-18 years.

HEPATITIS B

The rate of hepatitis B disease in adolescents hovered around 10 cases per 100,000 in the 1980s. A marked decline in incidence of the disease in children and adolescents accompanied the introduction of universal vaccination of these age groups in the 1990s. The largest decline (72.5%) occurred among adolescents; the rate has now fallen to about one case per 100,000.







ADOLESCENT VACCINES IN DEVELOPMENT

BETWEEN 2006 AND 2015, NEW VACCINES that will likely be targeted for administration to adolescents may become available to prevent infections from human papillomavirus (HPV), herpes simplex (HSV), cytomegalovirus (CMV), chlamydia and group B streptococci.

HPV is the cause of cervical cancer, which kills approximately 4,000 women per year. At present, the two vaccine candidates for HPV in the final stages of clinical development are only effective before exposure to HPV. HSV type 2 causes lifelong infection and significant medical and psychosocial morbidity. A vaccine has the potential to reduce HSV acquisition, disease severity and the number of cases of neonatal herpes, and it may also reduce transmission of HIV.

CMV infection is the most common intrauterine infection in the United States, causing congenital infection in children. A CMV vaccine administered to adolescent females would decrease morbidity and mortality by reducing the disease burden of congenital CMV infection.

By 2015, it is possible that vaccines against HIV and tuberculosis will be introduced; at least some of these will have the greatest benefit if administered to adolescents.

NUMEROUS VACCINES, LIMITED TIMEFRAME

WHILE VACCINES FOR ADOLESCENTS come with a virtual guarantee of effectiveness, they do not come with the additional time required to educate patients about the importance of being vaccinated. The problem becomes even more challenging with how to integrate the new vaccines into the delivery of the many other clinical preventive services recommended for adolescents. Medical staff can do most of the legwork required to screen for and inform patients and parents about the vaccines and the diseases they prevent. Patients can be given information on the vaccines at the time that they check in for their visit. The vaccine manufacturers will provide targeted materials about the new vaccines, and federally developed Vaccine Information Statements (VISs) are available at www.cdc.gov/nip/publications/VIS/default.htm. Besides presenting noncommercial information on each vaccine, the VIS is also available in many languages.

A greater challenge is integrating immunization into the array of clinical preventive services recommended in **Guidelines for Adolescent Preventive**Services (GAPS) and Bright Futures. GAPS consists of 24 recommendations that encompass healthcare delivery, health guidance, screening and immunization. Even more comprehensive, the Bright Futures initiative is a national health promotion and illness prevention initiative launched in 1990 to promote the health and wellbeing of infants, children, adolescents, families and communities.

One of the greatest challenges for the public health community is how to provide comprehensive preventive services for all adolescents. While more than 90% of adolescents report having a usual source of care, only two-thirds report having made a preventive visit in the last year. With special training, the proportion of the

recommended preventive services that can be delivered during a visit can increase but "gaps" remain.

Another tremendous challenge is uninsured or under-insured children, high school dropouts and youth confined in juvenile residential facilities. Fortunately, the VFC program makes vaccines available at no charge to almost all such youth. Children are eligible for the VFC program if they are under age 19 and either:

- Medicaid eligible
- Uninsured
- Under-insured (with insurance that does not cover immunizations) and being seen in a federally qualified health center or rural health center, or
- American Indian/Alaskan Native

Administration of recommended vaccines to adolescents continues to offer the potential to protect the health of both the individual adolescent and the public.

ADOLESCENT STAKEHOLDERS MEETING

A TWO DAY ADOLESCENT STAKEHOLDERS MEETING, sponsored by CDC and the National Vaccine Advisory Committee (NVAC), was held in Washington in June 2005. The meeting included over 140 key stakeholders with an interest in adolescent immunization. The objectives for this meeting were to identify issues expected to arise with the licensing of new vaccines for this age group and identify approaches that will most effectively increase adolescent vaccination. A series of white papers summarizing findings from this meeting will be published in *Pediatrics*. The NIP website also offers an adolescent area entitled "Vaccines for Teens: Vaccinate before You Graduate," available at www.cdc.gov/nip/recs/teen-schedule.htm. The site includes information about vaccines recommended for teenagers and provides links to information about vaccines for adults and children.







Lifelong Immunization ADULTHOOD

NTINUING EFFORTS IN ADULT IMMUNIZATION

NIP CONTINUES TO SUPPORT IMPROVED VACCINATION coverage for adults, including efforts to

- Improve physician and institutional practices for adult immunization
- Identify and overcome barriers to adult immunization that lead to substantially lower vaccination levels in African-American and Hispanic populations
- Connect immunization services to preventive health services for heart disease, asthma, diabetes, breast and cervical cancers, and other diseases
- Identify and prevent missed opportunities for vaccination in healthcare settings, the workplace, and other community areas
- Collaborate with partners to increase hepatitis B vaccination coverage rates among high-risk populations
- Work with partners and stakeholders to implement the 50 recommendations from the National Influenza Vaccine Summit

ENCOURAGING ADULT IMMUNIZATION

ONE OF THE GREATEST PUBLIC HEALTH CHALLENGES is extending the success in childhood immunization to the adult population. Illness caused by vaccinepreventable diseases is expensive in terms of dollars and, more importantly, human lives. Each year we spend many billions of dollars treating adults for vaccinepreventable illnesses, and each year, on average, more than 47,000 adults die from diseases that could have been prevented. (See the Disease Impact chart on page 32.) Fortunately, vaccines are available to prevent many potentially debilitating diseases, including influenza, pneumococcal disease, and hepatitis B virus infection. Hepatitis B vaccine provides protection against common causes of liver disease and liver cancer, making it the first vaccine that is effective in preventing cancers.

LONG-TERM CARE FACILITIES OFFER INFLUENZA AND PNEUMOCOCCAL VACCINATIONS TO RESIDENTS

AN ESTIMATED 1.6 MILLION TO 2 MILLION RESIDENTS are in approximately 18,000 nursing homes in the United States. Many are un- or under-immunized against influenza and pneumococcal disease. Based on 1999 CDC data, only 65% and 38% of nursing home residents had received influenza and pneumococcal vaccinations, respectively; the goal is to raise these levels to 90%.

VACCINES have been traditionally associated with protecting young children from childhood diseases. Increasingly, public health programs are focusing on the lifelong benefit that immunization brings. The National Immunization Program is involved in many efforts to protect adults from vaccinepreventable diseases that can affect us throughout life. After hearing from CDC and two industry groups—the American Association of Homes and Services for the Aging and the American Health Care Association—the Centers for Medicare and Medicaid Services (CMS) successfully established a new rule this year for influenza and pneumococcal vaccination of nursing home residents. As of October 1, 2005, all U.S. nursing homes enrolled in Medicare/Medicaid programs must provide these vaccinations to all eligible residents unless there is a documented medical contraindication, or they or their families choose not to have the vaccine(s).

"Vaccines against these diseases are effective in preventing hospitalizations and death," said CMS Administrator Dr. Mark McClellan, "however, many at-risk people are not getting the vaccines they need." While not specifically required by the new rule, the CMS statement also advised all facilities to provide annual influenza vaccination to their health care workers. CDC is planning to work with CMS to monitor and evaluate these efforts, with data expected to be available for review in mid-2006.

ADULT IMMUNIZATION SCHEDULE

NIP HAS ALSO RELEASED AN ADULT IMMUNIZATION SCHEDULE. First published in 2002, the schedule provides a readable summary of immunization recommendations for adults. The schedule is endorsed by the Advisory Committee on Immunization Practices, the American Academy of Family Physicians, and the American Academy of Obstetricians and Gynecologists. Versions of the schedule have been developed for clinicians and for the general public, available in both Spanish and English. The schedule, which can be downloaded and printed as a full-page document or as a pocket-sized card, can be found in the adult vaccination area of the NIP website at www.cdc.gov/nip/recs/adult-schedule.htm and is found on page 34 of this publication.

USE OF STANDING ORDERS IN NURSING HOMES

IN COLLABORATION WITH THEIR QUALITY IMPROVEMENT organizations, CMS and CDC recently completed a three-year program to promote standing orders for Medicare patients in nursing homes. Data showed that standing orders are both

more effective and more cost-effective than other types of immunization programs in nursing homes. In addition, CMS's Quality Improvement Organizations (QIO) were successful at increasing adoption of standing order programs in the nursing homes in the intervention states versus the control states. The study also demonstrated that signed consent is a major barrier to achieving higher vaccination rates in nursing homes. In response to this study, the American Medical Directors Association revised its tool kit for nursing home vaccination by removing the sample signed consent form. Four peer-reviewed publications have been published summarizing these study findings.



IMPACT OF ADULT VACCINE-PREVENTABLE DISEASES

	INFLUENZA (FLU)	PNEUMOCOCCAL DISEASES (PNEUMONIA, MENINGITIS, BACTEREMIA)	HEPATITIS B
DESCRIPTION	Highly infectious viral illness	Infectious illness caused by a type of bacteria (pneumococci)	A highly infectious disease of the liver caused by hepatitis B virus
SYMPTOMS AND SIGNS	Fever and chills, dry cough, runny nose, body aches, headache, sore throat	Pneumococcal Pneumonia Occurs when bacteria invade the lungs Symptoms may include high fever, cough with production of mucus, shaking chills, breathlessness, and chest pain that increases with breathing and coughing Pneumococcal Meningitis Occurs when bacteria invade the tissues and fluids surrounding the brain and spinal cord. Symptoms may include headache, stiff neck, fever, mental confusion and disorientation, and visual sensitivity to light. The disease can lead to coma and death. Permanent disabilities among some survivors of the disease include hearing loss (the most common), learning disabilities, mental retardation, seizures, and other sensory or motor problems. Pneumococcal Bacteremia Occurs when bacteria invade the bloodstream. Symptoms include fever and fatigue and can be accompanied by pneumonia and meningitis.	Frequently no symptoms, but if present can include yellow skin or eyes, tiredness, stomachache, loss of appetite, nausea, or joint pain. Hepatitis B can infect people without making them feel sick.
COMPLICATIONS	Pneumonia, exacerbation of chronic illnesses (such as heart and lung diseases), and death	Death. In the U.S., pneumococcal infections are one of the most common causes of death from a vaccine-preventable disease. <i>Additional Dangers</i> —Drug-resistant strains of pneumococcus are common. Almost a fifth of the isolates of pneumococci tested by the CDC in 2003 were resistant to penicillin.	Victims of this disease can suffer from lifelong liver problems such as scarring of the liver, chronic liver disease, and liver cancer.
TRANSMISSION	Contact with an infected person spreading the virus by droplets	Pneumococci are present in many people's noses and throats and, even if not causing illness, they can be transmitted to others through respiratory droplets. It is not known why some bacteria suddenly invade the body and cause disease.	Hepatitis B is spread when someone has contact with the blood of an infected person or has sex with an infected person. This is a highly contagious disease—100 times more contagious than the virus that causes AIDS. Sources of infection are not found for about one-third of those infected with hepatitis B.
IMPACT (in a typical year)	 Hospitalizations—Over 200,000 (more than 60% are 65 years old or older) Deaths—36,000 annually (more than 90% are 65 years old or older) During the 1990s, influenza epidemics caused 239,000 deaths. During the 20th century, three influenza pandemics caused more than 600,000 deaths. Direct medical costs—Over \$2 billion for hospitalized cases alone 	Pneumococcal Pneumonia Cases (hospitalized)—100,000 to 135,000 Deaths—12% of those infected with invasive pneumonia (mostly older adults) Pneumococcal Meningitis Cases—2,600 Deaths—18% of those infected with meningitis (mostly older adults) Pneumococcal Bacteremia Cases—more than 30,000 Deaths—9% of those infected (mostly older adults)	 Infections—Approximately 70,000 new infections occur each year, mostly in adolescents and adults. About 6% of these people become chronically infected and face a 15% to 25% lifetime risk of death from chronic liver disease. Deaths—About 1.25 million people in the United States suffer from chronic hepatitis B infection, and each year approximately 4,000 to 5,000 die prematurely from chronic liver disease.

USE OF PNEUMOCOCCAL CONJUGATE VACCINE IN THE ELDERLY

The only pneumococcal vaccine currently licensed for use with adults is the pneumococcal polysaccharide vaccine (PPV23), which provides limited protection for the elderly. NIP and Emory University are planning a clinical trial to determine if protection can be increased with a combination of PPV23 and the new pneumococcal conjugate vaccine (PCV7). This trial will assess the effectiveness of administering a combination of PPV23 and PCV7 given with and without a priming dose of tetanus vaccine. If a combination of vaccines is more effective than PPV alone, studies will be performed to measure how much better a combination protects the elderly from pneumonia. A small-scale pilot study was begun in January 2004; results from this study should be available in 2006.

ASSESSING PROGRESS IN ADULT IMMUNIZATION

ADULT CLINIC ASSESSMENT SOFTWARE APPLICATION

With funding and technical assistance from NIP, the American College of Physicians (ACP) has designed a three-year intervention to increase immunization rates among adult patients at high risk for vaccine-preventable diseases. Interested physicians, along with "immunization champions" from their office staff, participate in a one-day training session for NIP's Adult Clinic Assessment Software Application (ACASA). Participants leave the training session with a copy of ACASA loaded onto their laptops and then collect baseline immunization data using ACASA when they return to their offices. Using these data, ACP helps each practice pinpoint strengths, weaknesses, and gaps in patient immunizations. Using AFIX*, the NIP model for improving vaccination rates, ACP then works with each practice to increase its immunization rates.

In the first year of the project, ACP delivered customized ACASA data reports to 13 practices. Each of the 13 practices agreed to develop and implement plans to improve immunization rates and to measure progress over a three-year period. In the second and third years of the project, ACP will expand the number of participating practices to 25 per year; by the end of the 3-year period, ACP expects to conduct interventions in up to 70 practices.

NATIONAL INFLUENZA VACCINE SUMMIT

CDC'S NATIONAL IMMUNIZATION PROGRAM and the American Medical Association (AMA) co-sponsored the 2005 National Influenza Vaccine Summit in Chicago, Illinois, in May 2005. The Summit brought together over 150 representatives from over 60 public, private, and non-profit organizations—all stakeholders in the annual effort to administer influenza vaccine to over 185 million high-priority individuals each year.

The summit addressed three major areas of concern experienced in the 2004-2005 influenza vaccination season:

^{*}For more information about AFIX, see the Lifelong Immunization: Childhood section of this report.

RECOMMENDED ADULT IMMUNIZATION SCHEDULE BY VACCINE AND AGE GROUP*

UNITED STATES October 2005– September 2006



These recommendations must be read along with the footnotes that can be found on the last 2 pages of this schedule

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Approved by the Advisory Committee on Immunization Practices (ACIP), the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians (AAFP)

This schedule indicates the recommended age groups and medical indications for routine administration of currently licensed vaccines for persons aged \geq 19 years. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations, consult the manufacturers' package inserts and the complete statements from the ACIP (https://www.cdc.gov/nip/publications/acip-list.htm).

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available by telephone, 800-822-7967, or from the VAERS website at www.vaers.hhs.gov.

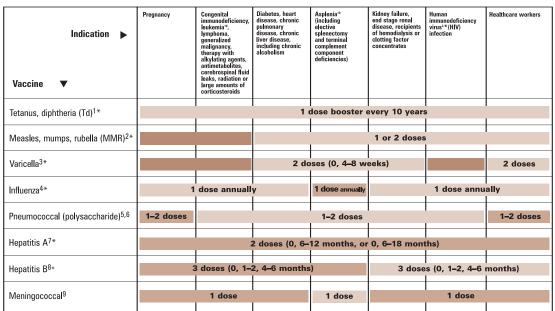
Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/osp/vicp or by telephone, 800-338-2382.To file a claim for vaccine injury, contact the

U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington D.C. 20005, telephone 202-357-6400.

Additional information about the vaccines listed above and contraindications for immunization is also available at www.cdc.gov/nip or from the CDC-INFO Contact Center at (800) CDC-INFO (232-4636) in English, en Español 24 hours a day, 7 days a week.

RECOMMENDED
ADULT
IMMUNIZATION
SCHEDULE
BY VACCINE
AND MEDICAL
AND OTHER
INDICATIONS*

UNITED STATES October 2005– September 2006



These recommendations must be read along with the footnotes that can be found on the last 2 pages of this schedule.

*Covered by the Vaccine Injury Compensation Program.



Approved by the Advisory Committee on Immunization Practices (ACIP), the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians (AAFP)

^{*}Covered by the Vaccine Injury Compensation Program.

^{*} Please see accompanying footnotes in the Annex of this publication.

- The lack of knowledge, indifference and/or frustration in the general public, priority persons and healthcare providers, addressing:
 - managing changing communications messages
 - managing different challenges facing immunization efforts during the upcoming 2005-2006 influenza vaccination season
 - driving increased vaccine uptake (extending the vaccination season), and
 - CMS efforts
- The stability of the influenza vaccine supply, and
- Enhancing influenza vaccine crisis planning in the areas of communications/ promotions, avian/pandemic preparedness, and an international perspective for pandemic influenza

The following primary action steps were proposed following the 2005 Summit:

- Hire full-time staff for the Summit
- Create and deliver a simple, unified communications campaign on influenza vaccination to:
 - commit to promoting vaccination widely and with a unified, audienceresearched message
 - develop a plan to promote vaccination into December and beyond
 - develop a Summit-supported universal vaccination message with priority group messages up front
 - encourage practitioners to extend access to their patients
 - educate healthcare professionals as well as their patients
 - establish routine influenza immunization for healthcare providers
 - educate for the first time the public about influenza cases with negative outcomes
 - promote live inactivated influenza vaccine to eligible individuals such as healthcare workers and school-aged children, and
 - use culturally appropriate messages and methods to reach underserved communities such as African Americans and Hispanics
- Work with the ACIP to simplify the influenza vaccine use recommendations
- Comment on the HHS Pandemic Planning Response and Participation Plans

2005-2006 INFLUENZA VACCINE SEASON

FOR THE 2005-2006 INFLUENZA SEASON, four manufacturers provided influenza vaccine in the United States: Chiron, GlaxoSmithKline, MedImmune, and sanofi pasteur. By January 2006, more than 80 million doses were distributed, and it is estimated that approximately 86 million doses were produced. Despite the total number of doses available, however, a delay in delivery occurred, and a decreased production of vaccines by one of the manufacturers resulted in a mismatch between supply and demand for influenza vaccine at the height of the vaccination season. This mismatch left a number of providers, facilities such as hospitals and long term care facilities, and vaccine distributors without sufficient vaccine.

To assess the extent of this mismatch, CDC performed systematic assessments of vaccine supply problems experienced by various key stakeholders, including state and local public health officials, private providers, other providers and facilities who

administer influenza vaccine, the public, and vaccine distributors, to understand the extent and duration of problems associated with vaccine supply and access to influenza vaccine this season. CDC also took steps to assess consumer demand for vaccine during the 2005-2006 influenza vaccination season. CDC surveyed physicians, hospitals, immunization grantees, community vaccinators, health departments, pharmacists, and others to better understand which providers had been affected by the influenza vaccine supply problems and to what extent. The information collected will help CDC evaluate and respond to challenges in the current influenza season and to plan for future seasons.

As part of its systematic assessment, CDC and AMA co-hosted more than 200 private and public health providers, vaccine manufacturers, and professional medical and health organizations for the fifth annual National Influenza Vaccine Summit. Summit participants met to review the 2005-06 influenza season to date, to identify and assess influenza vaccine ordering and distribution issues and vaccination activities undertaken in 2005-06, to discuss issues experienced during the 2005-06 influenza vaccination season, and to develop vaccination strategies and activities that could be implemented for future influenza seasons to foster effective use of influenza vaccines and high immunization rates. The National Influenza Vaccine Summit will issue recommendations to CDC on several topics including supply and distribution, communications, and improving vaccine demand.

Through CDC's Secure Data Network, CDC made available summary reports of influenza vaccine distribution data for the 2005-2006 influenza season. To aid the visibility of influenza vaccine distribution, CDC coordinated agreements with several distributors and one manufacturer to provide influenza vaccine distribution information to the ZIP-code level by type of provider on a weekly basis. This information was consolidated and mapped to common variables for reporting and then published to a secure environment in order to aid public health officials with the influenza vaccine season.

Throughout the year, CDC works with the ACIP to develop vaccine recommendations and to promote awareness and adoption of influenza vaccination recommendations through provider resources, patient and public education materials, media updates and public campaigns. Through the Section 317 program and the VFC Program, CDC distributes federal funds to states, territories, and some cities to purchase influenza vaccine. CDC also develops for this purpose vaccine contracts, on which states can purchase additional influenza vaccine with their own funds. CDC also creates and maintains the pediatric influenza vaccine stockpile (purchased through VFC funds) that provides a late-season strategic reserve of influenza vaccine.

CDC recognizes that it is necessary to ensure an enhanced and stable domestic influenza vaccine market to improve the response to both annual and pandemic influenza. CDC continually works to improve our response to vaccine shortages and to other unusual situations. We will continue to work with private industry manufacturers and our international partners to find solutions to the challenges we face related to influenza vaccine supplies.

Influenza Vaccine Supply On October 5, 2004, CDC was notified by Chiron

Corporation that none of its inactivated influenza vaccine (Fluvirin®) would be available for distribution in the United

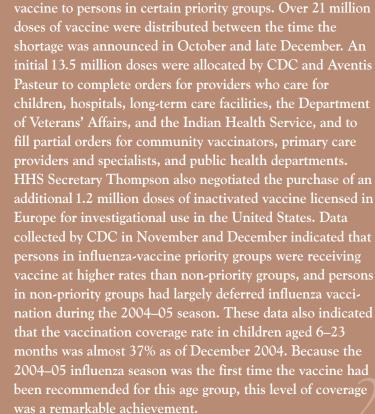
States for the 2004–05 influenza season, eliminating 46–48 million of an expected 100 million doses of inactivated vaccine. In coordination with the ACIP, CDC issued interim

recommendations to direct available inactivated influenza

SUPPLY

SUCCESS

STORY



As the flu season progressed, demand for vaccine by priority groups had been met in some areas, and additional supplies of vaccine became available. In response to these changed conditions, on December 24 CDC and ACIP released an update to the 2004-05 interim recommendations, which allowed vaccination not only for the priority groups defined on October 5 but for out-of-home caregivers and household contacts of persons in high-risk groups, and to all adults aged 50–64 years where vaccine supply was sufficient. However, mid-season vaccine coverage estimates among adults in priority groups were below estimates from the 2003-04 season. As 2005 began, ongoing efforts were needed to vaccinate persons in priority groups. CDC continued to work with Aventis Pasteur, Inc. to distribute the remaining supply of its inactivated influenza vaccine Fluzone® so that it reached persons in the priority groups.



Lifelong Immunization GLOBAL

PREVENTING DISEASE AROUND THE GLOBE

THE NATIONAL IMMUNIZATION PROGRAM is committed to working with partners to improve health in the United States and globally. We work closely with both established and new global partners to provide immunization expertise for global childhood immunization programs. We are committed to making polio eradication a reality, to pursuing efforts to eliminate or better control measles and rubella, and to helping developing countries use vaccines to control and prevent vaccine-preventable diseases.

FOR MOST VACCINE-PREVENTABLE DISEASES, no country is ever truly free of a disease until all countries are free. Working together, the countries of the world wiped smallpox off the face of the earth. The Centers for Disease Control and Prevention continues to lead collaborative efforts to protect every person in every country from vaccine-preventable diseases.

WORKING GLOBALLY TO STRENGTHEN ROUTINE IMMUNIZATION SERVICES

Approximately 2.2 million people die each year as a result of diseases that could have been prevented with currently available vaccines.* Vaccines that are now in the late stages of development or have been recently introduced in industrialized countries, such as the pneumococcal conjugate vaccine, could prevent almost two million additional deaths. CDC is therefore committed to improving access to sustainable and safe immunization services. Together with international partners, NIP is working to strengthen routine immunization activities, to reduce illness and death caused by vaccine-preventable diseases, and to build a strong platform for the introduction of new vaccines in the developing world.

In 2005, CDC continued to work with international partners at the regional and national levels to provide technical assistance to strengthen immunization programs, to improve health information systems and use of data, and to promote alignment with polio eradication and measles mortality reduction strategies. In addition, NIP collaborated with both the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in the development of their joint worldwide plan for immunization through 2015, the Global Immunization Vision and Strategies.

GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATION

CDC WORKS CLOSELY WITH THE GLOBAL ALLIANCE for Vaccines and Immunization (GAVI). This network of international partners was established to help the poorest countries strengthen childhood immunization programs, introduce new and under-utilized vaccines, improve injection safety in immunization programs, and fund research into the development of new vaccines. Through the generosity of partners such as the Bill and Melinda Gates Foundation, the vaccine fund currently is capitalized at more than \$1 billion, with more than 60 countries receiving GAVI funding support.

From 2001–2003, CDC served as the Technical Institute Representative on the GAVI Board. NIP staff continue to play an active role on GAVI's Monitoring and Evaluation Task Force. In this arena, NIP has provided technical support at the global, regional, sub-regional, and national levels in the implementation and evaluation of GAVI-related activities. Since January 2005, NIP has had a representative on the GAVI Working Group. This group develops and prepares working papers for the GAVI Board and helps set the direction of future GAVI activities. In addition, the Working Group sets the agenda for the bi-annual GAVI Board meetings as well as GAVI's Partners meeting.

Other partners of GAVI include WHO, UNICEF, the World Bank Group, the International Federation of Pharmaceutical Manufacturers Association, other public health and research institutions, and national governments.

THE GAVI MISSION

GAVI works to protect children of all nations and of all socio-economic levels against vaccine-preventable diseases.

GAVI has established six objectives to fulfill this mission:

- Improve access to sustainable immunization services.
- Expand the use of all existing safe and cost-effective vaccines and promote delivery of other appropriate interventions at immunization contacts.
- Support the national and international accelerated disease-control targets for vaccine-preventable diseases.
- Accelerate the development and introduction of new vaccines and technologies.
- Accelerate research and development efforts for vaccines needed primarily in developing countries.
- Make immunization coverage a center of international development efforts.

In 2002, working with other centers at CDC, NIP developed and published the strategic document, *Global Immunization*, 2002–2006: An Overarching Strategy for CDC. This document complements the current CDC global health strategy document, *Working with Partners to Improve Global Health:* A Strategy for CDC and ATSDR (published in September 2000) by providing specific

THE GAVI/HIB INITIATIVE: TAKING ACTION TO PREVENT CHILDHOOD PNEUMONIA AND MENINGITIS

information about CDC's health strategy for global immunization.

The mission of the GAVI/Hib Initiative is to expedite and sustain evidence-informed decisions at the global, regional and country levels regarding the use of Hib vaccination to prevent childhood meningitis and pneumonia.

The GAVI/Hib Initiative supports eligible countries in making informed decisions regarding the introduction or sustainability of Hib vaccine programs. This initiative is a collaboration between the Johns Hopkins Bloomberg School of Public Health, the London School of Hygiene and Tropical Medicine, CDC, and WHO and is funded by GAVI. The Hib



Initiative will build on ongoing activities that are relevant to Hib disease in the eligible countries and will work collaboratively with various partners to achieve the initiative's goal of reducing death and disability caused by meningitis and pneumonia.

In June 2005, the Hib Initiative was introduced at a WHO new-vaccines retreat in Geneva. In September and October, representatives of the Hib initiative visited WHO Regional offices in Europe, Africa, Southeast Asia, Western Pacific and the Middle East to discuss regional priorities and to select key countries for conducting on-site assessment of Hib vaccine issues. The first consultations with selected countries were conducted in Burkina Faso, Ukraine and Kyrgyzstan in November. The following month, the initiative was officially launched at a GAVI partners meeting in New Delhi, and in January 2006, the Hib Initiative held a retreat in Geneva to review the evolving environment of Hib immunization. This included new funding opportunities through GAVI, an evolving vaccine supply, and the new recommendation from the Strategic Advisory Group of Experts (SAGE).

The Hib Initiative is currently developing its strategic plan in collaboration with GAVI partners for submission to its management committee Spring 2006. The plan will focus on three main strategic directions: communication, coordination and research, and will focus its priorities by geographic areas with different levels of vaccine implementation. An extensive consultation process is underway that includes country visits, regional forums on Hib disease prevention, and coordination with other vaccine initiatives.

GLOBAL DISEASE DETECTION INITIATIVE

CDC and WHO conduct effective surveillance and laboratory confirmation for polio and measles on a global scale. These networks provide a platform on which to build sustainable surveillance and laboratory capacity for emerging infectious disease threats. In 2005, NIP's Global Immunization Division, together with the National Center for Infectious Diseases and WHO, began the Global Disease Detection Initiative. The purpose is to build capacity for high quality disease surveillance and to expand lab capacity to detect and confirm outbreaks from other diseases of global importance in Bangladesh, China, and India, which together represent over 2.5 billion people.

Based on input from host countries on disease surveillance and laboratory priorities, implementation of encephalitis and meningitis outbreak detection in high priority sites in the three countries were selected as targets for 2006. As CDC and WHO gain experience in-country with the management of these systems, this surveillance paradigm could be expanded to include additional countries and other syndromes in the future.

POLIO ERADICATION

SINCE THE WORLD HEALTH ASSEMBLY resolved to eradicate poliomyelitis globally, global polio eradication efforts have been very successful. Of the three types of wild polioviruses, type 2 was last seen in 1999 and appears to have been eradicated. Today, more than 200 countries and territories are certified polio-free, and the disease is now endemic in just four countries in South Asia and Africa. While

progress was made in 2005 in Egypt, India, Pakistan, Afghanistan, and Niger, poliovirus was imported into Indonesia, Yemen, Somalia, Angola, Ethiopia, Nepal, Sudan, Chad, Mali, Eritrea, and Cameroon as a result of suboptimal immunization activities. During 2005, reported confirmed cases of paralytic polio numbered 1,936,* compared to 1,255 reported cases in 2004. The 2005 figure represents a *case decline of more than* 99% since the World Health Assembly launched the global initiative to eradicate polio in 1988. Many challenges remain, however, as we strive to achieve and certify the eradication of polio.

SIGNIFICANT ACHIEVEMENTS IN POLIO ERADICATION

Vaccine Delivery

During 2005, CDC contributed more than 400 million doses of oral polio vaccine (OPV) through cooperative agreements with UNICEF and the United Nations Foundation to eradicate polio.

Supplemental Immunization Activities (SIAs)

Every country with endemic or recently endemic polio conducts supplemental immunization activities (SIAs) such as national or sub-national immunization days. During these activities, every child younger than five years of age receives two doses of oral polio vaccine, one month apart, regardless of prior immunization status. In 2005, an estimated 390 million children in 47 countries were reached as part of these efforts. Several endemic countries held multiple SIAs during the year. Nearly two billion doses of oral polio vaccine were delivered during SIAs in 2005.

Stop Transmission of Polio (STOP) Teams

Public health professionals are sent to host countries at the request of their Ministries of Health to support polio and measles surveillance as well as the planning, implementation, and evaluation of national immunization days. Since January 1999, over 675 STOP team members have participated in three-month assignments in 47 countries. This includes 37 NIP staff members who have participated on STOP teams, providing more than 3,300 person days in immunization activities, polio and measles surveillance, staff training, advocacy, and data management. This initiative has significantly enhanced each host nation's Expanded Programme on Immunization.

Surveillance

CDC and the Global Polio Eradication Initiative partners have intensified active surveillance for acute flaccid paralysis (rapid onset of floppy paralysis of arms and legs) and polio. In 2005, CDC helped conduct surveillance reviews in Bhutan, India, the Philippines, and South Sudan. In addition, CDC staff provided technical assistance to strengthen surveillance in other countries in Asia and Africa.

Laboratory Support

CDC assists WHO in building global polio and measles laboratory networks and serves as a WHO Global Specialized Reference Laboratory for polio. Reference laboratories are highly qualified laboratories that receive specimens from other laboratories for confirmation and also provide assistance with difficult specimens. To date, 145 laboratories are in the global polio network.

*WHO data as of February 28, 2006

Polio data for 2005 is provisional because cases are sometime reported as long as two months after onset of paralysis. Visit www.polioeradication.org for the latest polio statistics.



POLIO

SUCCESS

STORY

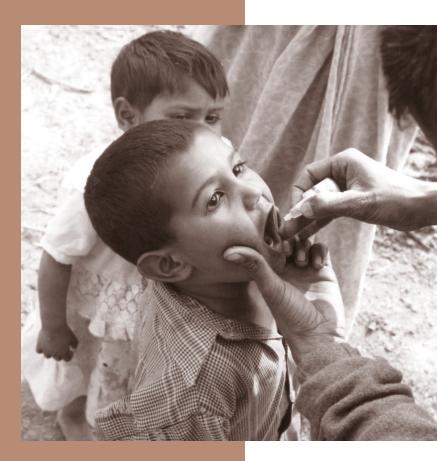
India and Egypt are two polio-endemic countries in which the government and partners achieved high polio vaccination coverage by 2004. However, due to factors such as dense population, poor sanitation, and high birth rates in some areas, polio virus continued to be transmitted efficiently in five reservoir areas in these countries. In September 2004, the WHO Advisory Committee

on Polio Eradication (ACPE) recommended using an old tool in the war on polio: a monovalent oral polio vaccine (mOPV) that has superior immunogenicity for the type of poliovirus circulating in the reservoir areas compared with the trivalent OPV that has been used to eradicate polio elsewhere.

Monovalent OPV was rapidly licensed for use in India and Egypt and was used in mass vaccination campaigns in the five reservoir areas from April to June 2005. Preliminary data provided very encouraging results: mOPV use appears to have stopped transmission of Type-1 poliovirus (P1) in three of five reservoirs and substantially reduced P1 transmission in the other two reservoirs.

In October 2005, based on this success, the ACPE recommended that mOPV use should immediately be expanded to interrupt transmission in all areas with circulating polioviruses.

Egypt



Partnerships

Collaboration among international partners continues to expand. This collaboration is unique among public health initiatives in its unprecedented level of joint activity, scale of private sector contributions, and funds raised. Rotary International alone projects a contribution of more than \$600 million (U.S. dollars) by 2005. The partners include CDC, Rotary International, UNICEF, WHO, the U.S. Agency for International Development, Japan, Great Britain, Germany, Canada, Denmark, Australia, the Netherlands, the Task Force for Child Survival and Development, the United Nations Foundation, the Bill and Melinda Gates Foundation, World Bank, the International Federation of Red Cross and Red Crescent Societies, Aventis Pasteur/IFPMA, and other international agencies.

Activities that have worked so well in reducing and eliminating polio will continue. These activities include:

- Accelerating immunization activities and intensifying surveillance in all polio-endemic countries, particularly those affected by war or civil unrest
- Supporting coordinated, planned strategies for polio eradication based on strong routine immunization programs, National Immunization Days, acute flaccid paralysis surveillance, and "mopping-up" immunization
- Supporting the STOP Program to ensure that a cadre of trained public health professionals works in high-priority countries to accelerate polio eradication, accelerate measles mortality reduction and regional elimination, and improve disease data management
- Continuing research and developing consensus for how to achieve polio eradication, post-eradication immunization policy and support for laboratory containment of the polio virus
- Moving forward with the certification process for countries that are poliofree but not yet certified
- Seeking the additional financial and human resources to fully implement the WHO-recommended strategies for polio eradication in Africa and Asia
- Providing more than 2300 person days to support polio eradication in the field in 2005 (not including CDC STOP volunteers)

MEASLES MORTALITY REDUCTION AND REGIONAL ELIMINATION EFFORTS

MEASLES IS NO LONGER ENDEMIC in the United States. This means that all of the cases now seen in our country were either documented or believed to have been brought in from other countries. The number of cases in the Western Hemisphere has been reduced by more than 99% from approximately 250,000 cases in 1990 to 75 cases in 2005.* And measles importations in the United States from Latin America have also dropped from 230 cases in 1990 to no cases during 2000–2004.

However, measles remains rampant in other parts of the world. In 2003, measles was responsible for an estimated 530,000 deaths in developing countries, and it was the leading cause of vaccine-preventable death for children under 5 years of age. CDC, in partnership with WHO, UNICEF, the American Red Cross, and the United Nations Foundation, agrees that there is an urgent need to accelerate global measles control.

^{*}Pan American Health Organization, December 31, 2005







TOP: **Chad** — NIP's Robert Perry watches a measles vaccination post

CENTER: **Bangladesh** — Meredith McMorrow with surveillance officers on measles training

BOTTOM: **Angola** — Polio immunization day

MEASLES INITIATIVE CONTINUES

The American Red Cross, CDC, the United Nations Foundation, the World Health Organization, and the United Nations Children's Fund continue to support the Measles Initiative, a five-year program to control measles deaths in Africa by vaccinating 200 million children in 36 sub-Saharan countries by 2005. While most Americans barely remember measles, this disease kills many thousands of children worldwide annually, an estimated 216,000 in Africa alone. This fact makes measles the single leading vaccine-preventable cause of death among children in Africa, yet it can be easily prevented with a simple vaccination. To date, more than 200 million children have been vaccinated in more than 40 countries, preventing an estimated 1.2 million measles deaths. For more information about the Measles Initiative, visit www.measlesinitiative.com.

ACHIEVEMENTS IN MEASLES REDUCTION AND ELIMINATION

Partnership

CDC has played a leading role in establishing a new partnership to champion measles control efforts and prevent the annual measles deaths still occurring worldwide. The partnership includes WHO, UNICEF, the American Red Cross, the United Nations Foundation, and the International Federation of the Red Cross and Red Crescent Societies. In five years, the partnership immunized more than 200 million children and prevented an estimated 1.2 million measles deaths, reducing measles mortality in sub-Saharan Africa by 60% from 1999–2004.

Strategies

A three-pronged strategy has been responsible for many successes in global measles reduction, such as the dramatic drop in measles cases in the Western Hemisphere and the elimination of endemic measles in the United States. The strategy consists of the following approaches:

- Supplementary immunization activities to rapidly increase population immunity against measles (a "second opportunity" for measles immunization)
- High routine coverage with at least one dose of measles vaccine
- Integrated epidemiologic and laboratory surveillance

SUPPORT

During 2005, CDC supported measles mortality reduction in the African Region—AFRO (Chad, Comoros, Cote d'Ivoire, Equatorial Guinea, Kenya, Mozambique, Nigeria, and South Africa), the Eastern Mediterranean Region—EMRO (Egypt, North and South Sudan, and Somalia), the Southeast Asia Region—SEARO (India, Bangladesh, and Indonesia), and the Western Pacific Region—WPRO (China, Japan, Pacific Island Countries, and Philippines). In addition, CDC supported regional measles elimination activities in the Region of the Americas (Argentina, Columbia, Guatemala, Mexico, and Peru) and the European Region—EURO (Azerbaijan, Kazakhstan, Kyrgyzstan, Romania, Tajikistan, and Turkey).

SIGNIFICANT ACCOMPLISHMENTS

During 2005, only 75 measles cases were confirmed in the Western Hemisphere compared to 2,572 confirmed cases in 2002.* The majority of these cases were imported from measles-endemic countries outside the Western Hemisphere. No sustained measles transmission has been reported in the Americas since November 2002. In fiscal year 2005, CDC contributed approximately \$42 million in grants and other scientific and technical assistance to control measles globally, as compared with a contribution of approximately \$28 million in fiscal year 2002.

CONTINUING COMMITMENT TO MEASLES REDUCTION AND ELIMINATION

Measles activities will continue, moving toward the reduction and elimination of another deadly vaccine-preventable disease and improving health and quality of life for people everywhere.

These activities include:

- Supporting accelerated measles control by focusing efforts in priority countries in each WHO region:
 - For AFRO: Angola, Chad, Kenya, and Nigeria for technical assistance for campaigns and strengthening of surveillance, and all countries in the Central Block
 - For SEARO: India and Indonesia
 - For WPRO: China, Japan, Pacific Islands (Including U.S.-affiliated Pacific jurisdictions)
 - For EURO: Russian Federation, Western Europe
 - For EMRO: Sudan
- Eliminating measles, rubella, and congenital rubella syndrome in the Western Hemisphere, in cooperation with the Pan American Health Organization (PAHO), by strengthening surveillance, outbreak investigation and response, routine immunization and implementation of vaccination strategies, and epidemiological and laboratory capabilities
- Implementing the Global Measles Strategic Plan (2001–2005) with partners for measles-related mortality reduction and regional elimination of the disease and collaborating with WHO and UNICEF to develop the 2006–2010 Strategic Plan
- Building epidemiologic and laboratory surveillance capability
- Evaluating vaccination strategies for elimination, mortality reduction, and accelerated control
- Promoting injection safety and development of new injection tools
- Increasing the capacity of ministries of health to evaluate supplementary immunization campaigns
- Conducting research to determine the impact and cost-effectiveness of linking the delivery of immunizations with other public health interventions such as bednets to prevent malaria and follow-up services of infants born to HIV-infected mothers.



Mexico — NIP's Ismael Ortega-Sanchez conducts an Economic and Prevention Effectiveness Training on Rubella and CRS in Mexico City. NIP is in a research collaboration with the Mexican Department of Health as partners in the goal of eliminating Rubella and CRS in the Americas

^{*}Pan American Health Organization, December 31, 2005

MEASLES

SUCCESS

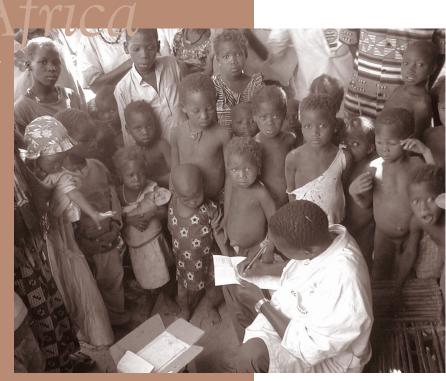
STORY

A dramatic drop in measles deaths in Africa has punctuated the success of immunization efforts on that continent.

Measles strikes hardest against the most vulnerable children—especially the malnourished and infants. Of all regions, Africa has had the largest burden of measles deaths, with an estimated 519,000 deaths in 1999. But the rate of mortality from measles has been declining sharply—and rapidly. From 1999 to 2004, measles deaths fell 60% in Africa, an indication that measles mortality reduction efforts are actually proceeding ahead of schedule.

The support of the Measles Initiative, which has helped implement large-scale immunization campaigns in Africa, has been an important factor in this decline. The goal of the five-year initiative (2001–2005) is to reduce global measles deaths by 50% by the end of 2005, compared to 1999 figures.

The Centers for Disease Control and Prevention, the American Red Cross, the United Nations Foundation, the World Health Organization, and UNICEF are all founding members of the Measles Initiative. Other key partners in the initiative include the International Federation of Red Cross and Red Crescent Societies, the Gates Foundation, the Canadian International Development Agency, and countries affected by measles.



60% reducti

JNIZATION PROGRAM **2006 ANNUAL REPORT**

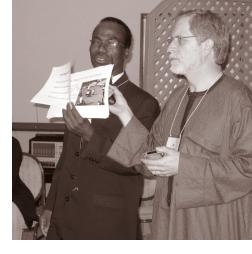
INTEGRATING HEALTH INTERVENTIONS TO SAVE ADDITIONAL LIVES

IMMUNIZATION CAMPAIGNS provide the perfect opportunity to deliver additional health interventions—such as insecticide-treated bed nets (ITNs) to prevent malaria—because health workers access nearly all of a country's mothers and young children during a campaign. While integrated campaigns have been piloted in parts of Ghana and Zambia in the past, the West African nation of Togo implemented the first nationwide integrated health campaign in mid-December 2004 with the support of the Measles Initiative. A post-campaign evaluation revealed that more than 90% of eligible children received measles and polio vaccines, de-worming medicine, and ITNs. The campaign proved that multiple interventions can be delivered successfully during an immunization campaign. The integrated strategy has the potential to save thousands of additional lives and saves governments money by combining interventions to the same target group. Integrated campaigns are planned in at least nine countries in 2006, including Indonesia, Ghana, Kenya, and Angola.

STRENGTHENING CHILDHOOD IMMUNIZATION

MORE THAN TWO MILLION PEOPLE—mostly children—die each year from vaccine-preventable diseases such as measles, Hib, pertussis, and neonatal tetanus. One of the primary strategies for reducing these deaths, as well as for achieving polio eradication, is to improve routine immunization coverage in countries where this is low. Since 2004, CDC has worked with WHO, UNICEF, and ministries of health in high risk districts in priority countries to improve routine immunization coverage. The Strengthening Childhood Immunization Team at NIP works with these partners to help assess the feasibility of integrating the delivery of additional health interventions—such as the prevention of mother-to-child HIV transmission and the distribution of bed nets for malaria prevention—with routine immunization in Kenya, Malawi, and Zimbabwe.

The team also works with partners on operations research projects to test strategies for improving routine immunization in India, Kenya, and Burkina Faso. The Kenya and Burkina Faso projects have shown significant increase in routine immunization coverage in the intervention districts. For example, 5,000 additional children were vaccinated against measles per year in the three pilot districts in Kenya than prior to the intervention, an increase of 54.1%, and in Burkina Faso, there was a 21% increase in the number of children vaccinated against measles in the three pilot districts. The improved coverage is attributed to supportive supervision and using data for program planning and program feedback. These countries plan to expand the use of these strategies to boost routine immunization rates nationwide.







TOP: **Nigeria** — Dr. Steve Wasilak conducts a polio training class

CENTER: **India** — Young polio patients enjoy a visit from Dr. Steve McLaughlin

BOTTOM: **Kyrgyzstan** — Dr. John Moran reviews a laboratory log book with the head of the bacterial lab during a Hib Initiative visit

Leadership in Vaccine SAFETY & SCIENCE

SAFETY & SCIENCE OF VACCINES

The Immunization Safety Office includes six primary activities:

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink Project (VSD)
- Clinical Immunization Safety Assessment (CISA) Network
- The Brighton Collaboration
- The Vaccine Technology Development (VAXDEV) Activity
- Vaccine Acceptance and Risk Perception

IMMUNIZATION SAFETY OFFICE

AS A LEADER IN IMMUNIZATION SAFETY RESEARCH and surveillance, CDC plays a vital role in assuring vaccine safety. Sound immunization policies and recommendations affecting the health of our nation depend upon continuous monitoring of vaccines and ongoing assessment of immunization benefits and risks. Serious adverse events after vaccination occur but are generally rare. Even with well designed, large, pre-licensure clinical trials, it is difficult to detect rare adverse events. Therefore, post-marketing monitoring of adverse events after vaccination is essential. Using a multi-faceted approach, CDC identifies possible vaccine side effects, conducts epidemiological studies to determine whether a particular adverse event is caused by a specific vaccine, helps determine the appropriate public health response to vaccine safety concerns, evaluates public and healthcare provider perceptions of vaccination, and communicates the benefits and risks of vaccines to the public, media, and healthcare communities.

In 2005, as part of a broad reorganization of the CDC, the Immunization Safety Branch was renamed the Immunization Safety Office (ISO) and moved from the National Immunization Program into CDC's Office of the Director, Office of the Chief Science Officer. The reorganization was undertaken as part of CDC's efforts to create more robust immunization safety activities. An independent operating budget was created for the Immunization Safety Office. The separation of safety monitoring and programmatic budget and reporting lines will ensure that both activities receive the attention and support needed to make certain they are equally dynamic and robust.

These steps were taken following a series of efforts by CDC to obtain input about its immunization safety activities from health professionals, scientists, policy makers, and parents:

- In 2004, CDC convened a Blue Ribbon Panel of health and safety science professionals to provide their independent assessments of CDC immunization safety activities.
- CDC heard directly from parents and concerned citizens about its autism research activities, including possible associations with vaccinations, through a series of meetings held in communities across the nation.
- CDC also asked for assessments from its own scientists and health professionals.

CDC continues to invite input from others regarding its efforts to strengthen its immunization safety focus, resource allocations, oversight and review efforts.

The functions of the six ISO primary activities and highlights of their recent accomplishments are described in the following text.

THE VACCINE ADVERSE EVENT REPORTING SYSTEM

THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) is required under federal law to serve as a program for vaccine safety monitoring. It is jointly administered by CDC and the Food and Drug Administration (FDA) and functions as an "early warning" system to help identify rare vaccine side effects. VAERS accepts reports from vaccine recipients, parents and guardians, healthcare providers, and all others for any suspected adverse event following immunization, even if there is no proof that the event was caused by a vaccine. A cornerstone of vaccine safety monitoring, VAERS supports the collection, review, and analysis of reported adverse events. CDC and FDA have published and presented many vaccine safety studies based on VAERS data.

In 2005, VAERS identified Guillain-Barré Syndrome (GBS) as a possible rare serious side effect following the newly licensed meningococcal conjugate vaccine (Menactra®). Investigation of a possible causal association is currently ongoing. In the interim, the VAERS findings have resulted in educational and outreach efforts targeted to health care providers and changes to the vaccine's recommendations and instructions for use.*

Also in 2005, VAERS researchers from CDC and FDA published summaries of safety data on use of influenza vaccines in 6–23-month-old children and on the first two years of use of the live attenuated influenza vaccine (FluMist®). These safety data provide vital information in a setting in which public health authorities are considering further expanding recommendations for use of influenza vaccines and preparing for response to a possible influenza pandemic.

The VAERS program continued its work with the HHS voluntary civilian smallpox vaccination program to monitor smallpox vaccine adverse events for both civilian and military populations. VAERS monitoring helped identify myocarditis and pericarditis following vaccination and led to changes in information and educational materials for smallpox vaccines. By the end of 2005, VAERS data had supported the publication of at least five peer-reviewed journal articles which will provide the safety knowledge base for any future use of smallpox vaccine. System enhancements to VAERS in response to preparation for the smallpox program improved CDC's capacity to respond to mass immunization campaigns associated with vaccine-preventable disease threats.

General VAERS information and online reporting capability are available on the Web at www.vaers.hhs.gov. Secure Web-based reporting has been available since 2002 and has resulted in more timely and complete reporting to VAERS. Further evaluation of online reporting is ongoing as part of system wide quality improvement efforts. In collaboration with the Department of Defense and others, VAERS conducted the first comprehensive evaluation of healthcare provider knowledge and behaviors related to adverse events following immunization. Findings from this study will be used to develop strategies for improved education and training of potential reporters.

THE VACCINE SAFETY DATALINK

THE GAPS THAT EXIST in the scientific knowledge of and the capacity to scientifically evaluate possible vaccine adverse effects prompted the CDC to develop the Vaccine Safety Datalink (VSD) project in 1990. This project has proven to be a powerful and cost-effective tool for the ongoing evaluation of vaccine safety. The VSD project involves partnerships with several large health maintenance organizations (HMOs) to conduct high quality scientific evaluations of important immunization safety questions. VSD is an example of a large-linked database and includes information on more than six million people. All vaccines administered within the study population are recorded. Available data include vaccine type, date of vaccination, concurrent vaccinations (those given during the same visit), the manufacturer, lot number, and injection site. Medical records are then monitored for potential adverse events resulting from immunization. The VSD project allows for planned vaccine safety studies as well as timely investigations of new hypotheses. A focus of VSD research is the evaluation of the safety of new vaccines and changes in the immunization schedule. Specific VSD study questions or hypotheses result from the medical literature, the Vaccine Adverse Event Reporting System, and issues of concern to the public. Since its inception, the VSD project has resulted in scores of publications in leading medical and scientific journals, and the findings of VSD studies have had major impacts on guiding national immunization policies and recommendations.

During 2005, new methodologies that enhanced the timeliness of data availability and analysis were implemented and allowed VSD to provide rapid assessments of influenza vaccination coverage during a year of influenza vaccine shortage. The rapid assessment methodology is now being used to monitor the safety of newly licensed vaccines, such as Menactra (quadrivalent meningococcal conjugate vaccine).

SELECTED VACCINE SAFETY STUDIES IN 2005

Active Surveillance of Vaccine Safety: A System to Detect Early Signs of Adverse Events

Recent events in the United States have underscored the need for surveillance systems that detect adverse events as soon as possible after the introduction of new vaccines or the reintroduction of old vaccines to new populations. With no population-based systems in the United States to rapidly detect adverse events to such vaccines, this study evaluated the feasibility of developing such a system. Investigators for this study used five years of data from four HMOs participating in the VSD Project. These proof-of-concept analyses indicated that the rapid detection methodology was able to detect an increase of intussusception shortly after the introduction of rotavirus vaccine. Decreases in risk for fever, seizures, and other abnormal neurologic events became detectable within 12 weeks, 42 weeks, and 18 months, respectively, after the change from DTPw (formulation with whole-cell pertussis) to DTPa (formulation with acellular pertussis).

Davis RL, Kolczak M, Lewis E, Nordin J, Goodman M, Shay DK, Platt R, Black S, Shinefield H, Chen RT. Active surveillance of vaccine safety data for early signal detection. Epidemiology 2005; 16(3):336-41.

Rapid Assessment of Influenza Vaccination Coverage Among HMO Members —Northern California Influenza Seasons, 2001-02 through 2004-05

Beginning with the 2003-04 influenza season, the VSD team and Kaiser Permanente Northern California (KPNC) established a system to apply the rapid detection methodology to monitor potential adverse events following adult and pediatric influenza vaccinations. In response to the influenza vaccine shortfall and resulting prioritization of the vaccine distribution during the 2004-05 influenza season, the rapid analysis system was utilized to allow the VSD and KPNC to carry out rapid weekly assessments of influenza vaccination coverage levels. This rapid analysis of influenza vaccination coverage indicated that KPNC effectively followed Advisory Committee on Immunization Practices (ACIP) prioritization guidelines and focused their vaccination efforts on children aged 6–23 months and persons aged 65 years and older. The final influenza vaccination coverage levels for the 2004-05 influenza season for KPNC were 57% for children aged 6–23 months, 7% for children aged 2–17 years, 6% for persons aged 18–49 years, 24% for persons aged 50–64 years, and 72% for persons aged 65 years and older.

VSD Analysis on Hepatitis B Vaccine and Risk of Multiple Sclerosis

In April 2005, a VSD analysis on hepatitis B vaccine (HBV) and risk of multiple sclerosis (MS) was published as a letter in the journal *Neurology*. The analysis was done in response to a controversial study which reported finding an increased risk of MS within three years of hepatitis B vaccine administration. The study was controversial as no previous epidemiologic study had found a significantly increased risk, and the Institutes of Medicine had previously determined that the evidence favored rejection of a causal association. The VSD investigators attempted to replicate the study by reanalyzing the data from a VSD study of MS. No increased risk of MS was found in any time interval, including the first three years after hepatitis B vaccination. The study results from the VSD reanalysis support the weight of the evidence that hepatitis B vaccine does not cause MS.

Other studies addressing important immunization safety questions that are currently in progress include:

- A multi-site case-control study of the **risk of autoimmune disease** following hepatitis B vaccination
- An assessment of the risk of idiopathic thrombocytopenia purpura (ITP) following MMR vaccination
- An assessment of the safety of the inactivated influenza vaccine among children ages 6–23 months
- Studies to determine whether **hepatitis B vaccine is associated with an increased risk of alopecia** in adults and adolescents
- A multi-site, case-control study to assess risk of Bell's palsy following influenza vaccination
- A multi-site, case-control study to investigate the **relationship between** thimerosal and the onset of autism
- A follow-up neurodevelopmental assessment of children who were exposed to different amounts of thimerosal in vaccines as infants

Influenza Vaccination Coverage Among HMO Members— Northern California Influenza Seasons, 2001-02 Through 2004-05. MMWR 2005;54(27): 676-8.

CDC. Rapid Assessment of

DeStefano F, Weintraub ES, Chen RT. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study (letter). Neurology 2005;64(7): 1317.

CLINICAL IMMUNIZATION SAFETY ASSESSMENT NETWORK



TO ADDRESS NATIONAL UNMET IMMUNIZATION safety research needs, the CDC funded the establishment of the Clinical Immunization Safety Assessment (CISA) Network in 2001. CISA is a national network of six medical research centers with expertise in immunization safety. The network includes epidemiologists, clinician researchers, and vaccine investigators who are at the forefront of their fields. The CISA network offers healthcare providers with expert opinion on immunization-related medical evaluation, diagnosis and management. The network focuses on select cases of rare vaccine adverse events that have been reported to VAERS.

The network's mission is to conduct clinical research of immunization-associated health risks to provide clinicians with evidence-based counsel and empower individuals to make informed immunization decisions. The CISA network findings will assist domestic and global vaccine safety policymakers, thereby enhancing public confidence and sustaining immunization benefits for all populations. Through these standardized case investigations, the CISA Network envisions that its research will assist in "making immunizations as safe as possible."

CISA PRIORITY ACTIVITIES FOR 2005

- Enrolling subjects in the newly established Centralized Registry of Clinical Data and Repository of Biological Specimens
- Improving our understanding of hypersensitivity reactions following immunization
- Improving our understanding of how to assess causality in relation to adverse events following immunization
- Enrolling subjects in specialized protocols such as clinical evaluation of patients with serious adverse events following yellow fever vaccine administration
- Studying unexpected or serious adverse events for newly licensed vaccines (e.g., Guillain-Barré Syndrome among adolescents who received meningococcal conjugate vaccine)
- Increasing collaboration with existing immunization safety research activities (e.g., Brighton Collaboration, Vaccine Safety Datalink, Vaccine Adverse Event Reporting System, Vaccine Acceptance and Risk Perception, as well as the Department of Defense and global collaborators).

THE BRIGHTON COLLABORATION



THE BRIGHTON COLLABORATION WAS FORMED in fall 2000 to develop case definitions for adverse events following vaccination. The Collaboration has an international membership of volunteer participants with backgrounds in patient care, academic research, public health, vaccine clinical trials, and regulatory or manufacturing issues. The Collaboration developed and published six case definitions for adverse events that are of particular concern to parents, including persistent crying, fever, hypotonic-hyporesponsive episode, intussusception, nodule at injection site, and seizure.

In 2005, the Brighton Collaboration grew from 535 to over 800 participants in 71 countries (up from 59 countries). Twelve scientific working groups are currently developing 20 case definition and guideline documents. The guidelines cover general considerations, clinical trials, data collection, analysis, and presentation for surveillance systems. In 2005, the topics the work groups addressed included anaphylaxis; fatigue; abscess and cellulitis and induration and swelling at injection site; rash; unexplained sudden death, including sudden infant death syndrome; thrombocytopenia; eczema vaccinatum; generalized vaccinia, inadvertent inoculation vaccinia, progressive vaccinia, and robust take; encephalitis/myelitis/acute disseminated encephalomyelitis and aseptic meningitis; data collection guidelines in neonatal clinical trials; and case definition with guidelines for Guillain-Barré syndrome.

More than 300 scientists have requested case definition and guidelines directly from the Brighton Collaboration for use in clinical trials and surveillance systems. Additionally, the Food and Drug Administration (FDA), the European Medicinal Agency (EMEA), and the Council for International Organizations of Medical Sciences (CIOMS) have made favorable mention for use of Brighton Collaboration case definition and guidelines in clinical trials and surveillance systems.

THE VACCINE TECHNOLOGY DEVELOPMENT ACTIVITY

THE VACCINE TECHNOLOGY DEVELOPMENT (VAXDEV) Activity focuses on a variety of technological initiatives, projects, standards, and applied research which enhance the safety of immunization, promote improved systems and practices for monitoring vaccine safety, and otherwise promote the research, development, uptake and monitoring of new and safer vaccines (www.cdc.gov/nip/dev).

A major priority is promoting safer, simpler, and swifter vaccine delivery technologies to overcome the following dangers and drawbacks of using needle-syringe to administer vaccine:

- Unsterile needle reuse in developing countries
- Needle phobia, discomfort to patients
- Needle-stick injuries to health care workers
- Parental resistance to increasing numbers of recommended childhood "shots"
- Sharps waste disposal complexity and costs

VAXDEV activities in 2005 included work with needle-free jet injection technologies. In order to overcome the various drawbacks and dangers of vaccination with conventional needle and syringe, VAXDEV undertakes efforts on several fronts to develop and promote vaccination by needle-free jet injection and aerosol inhalation. The Immunization Safety Office has supported the development of a new generation of safe, needle-free, high-speed disposable-cartridge jet injectors, which have reached the working prototype stage (LectraJet®) with testing completed in animals. VAXDEV collaborated with the VSD site in Seattle in their conduct of a clinical trial of influenza vaccination with standard 0.5 mL and reduced doses delivered by needle-free injectors compared to needle-syringe. The activity also implemented a vaccine study entitled "Clinical Trial of Safety (Reactogenicity) and Immunogenicity of Needle-free Jet Injection of Reduced-dose, Intradermal Influenza

Vaccine (INF) Administered to 6-Month to Under 24-Month-Old Infants and Toddlers in the Dominican Republic." This clinical trial is scheduled to begin in 2006. VAXDEV maintains a website to educate the public and serve as a scientific resource for needle-free injection technology (www.cdc.gov/nip/dev/jetinject.htm).

VACCINATION VIA THE RESPIRATORY TRACT

VAXDEV leads a CDC effort with multiple outside partners on research focusing on the lungs as the target tissue for antigen delivery.

Aerosol Vaccination Device: Aerosol vaccination has been shown to be an effective way to deliver measles vaccine; however, the equipment for aerosol vaccination is cumbersome and has many technical limitations. CDC developed AeroLife™ through a small business innovation research (SBIR) contract with a research engineering company. This aerosol vaccination device overcomes the previous limitations and is designed for mass measles vaccination. The device was fully successful in license-level toxicology studies. Clinical trial prototypes have been manufactured and clinical trials are expected to begin in 2006. CDC has licensed the technology to AerovectRx, Inc., a private company that intends to obtain regulatory licenses and manufacture and distribute the AeroLife™ device. Research is also underway on aerosol delivery of siRNA (small interfering Ribonucleic Acid) in collaboration with the University of Georgia. The prototype model is intended to inhibit respiratory syncytial virus.

Measles Aerosol Project: CDC is a key partner with WHO and the American Red Cross in the Measles Aerosol Project. The goal of this project is to perform the necessary toxicology research and clinical trials to license at least one aerosol device/measles vaccine combination for use in developing countries. License-level toxicology studies have been completed and clinical trials are expected to begin in India and Mexico in 2006. This project is funded by the Bill and Melinda Gates foundation for \$7 million.

Measles Dry Powder Vaccine for Inhalation: Through an SBIR project, CDC worked with AktivDry, Inc. to develop a dry powder measles vaccine and test the potency in the CDC Measles Laboratory. Early dry powder measles vaccine formulations were successful in principle. CDC worked with AktivDry and many other partners including WHO, the Serum Institute of India (SII—the world's largest measles vaccine manufacturer), and the University of Colorado to develop a five-year project to refine the formulation, complete regulatory testing and establish dry powder measles vaccine production capacity. At the end of 2005, this project was funded at over \$19 million under the Gates Grand Challenges in Global Public Health grant program.

VACCINE ECONOMICS

VAXDEV described a new philosophical approach and promoted a new operations research tool for vaccine purchasers to select the lowest-overall-cost formulary that will satisfy the recommended childhood immunization schedule. It competes existing and proposed monovalent and combination vaccines on distinguishing features as incentives for market-driven product innovation. VAXDEV also conducted in-house studies on vaccine wastage and collaborated with outside researchers on "willingness"

to pay" surveys to assess the value of pediatric combination vaccines in reducing the number of injections.

INJECTION SAFETY

In collaboration with Emory University and Georgia Institute of Technology, NIP's Immunization Safety Office is currently researching and developing technologies to reduce the dangers of needle sticks, unsafe medical waste disposal, and unsterile reuse of needles, by studying medical waste disposal practices in Mexico. The economic benefits of these new technologies are being explored through this cooperative.

VACCINE IDENTIFICATION STANDARDS INITIATIVE

The Vaccine Identification Standards Initiative (VISI) is a cooperative effort by CDC and partners in the vaccine and immunization system, aiming to establish uniform standards for vaccine packaging, labeling, and recording. Its goal is to reduce the risk of medical errors and make it easier to accurately transfer immunization information into medical records and immunization registries. Improved recordkeeping helps researchers monitor adverse reactions following vaccination and track vaccine lots for safety surveillance. VISI guidelines include bar-coded, peel-off stickers on vaccine vials and pre-filled syringes as well as standardized requirements for information in carton sidebars. On April 26, 2004, the FDA began to require bar codes on all new unit-of-use packaging of drugs, including vaccines—an important first step toward fulfilling VISI recommendations. By April 26, 2006, such bar coding must be applied to all existing products.

VACCINE ACCEPTANCE AND RISK PERCEPTION ACTIVITIES

THE VACCINE ACCEPTANCE AND RISK PERCEPTION (VARP) team conducts ongoing research to

- Better understand how individuals interpret risks and make vaccination decisions
- Determine how best to communicate with different groups of people about the need for vaccination and the risks and benefits of vaccines
- Develop and evaluate interventions that help individuals make informed decisions about vaccinations

Research is underway to address each of these goals. In 2005, an international study in collaboration with the World Health Organization was initiated to better understand the vaccine safety perceptions of parents in developing countries. Staff visited three countries, Kazakhstan, Uzbekistan and Uganda, working with incountry public health staff to conduct a survey of parents.

Also in 2005, efforts were continued to develop and test tailored educational materials for parents about childhood immunizations. An increasing number of parents, as well as healthcare providers, have little or no personal experience with or knowledge of many of the diseases that childhood immunizations prevent. Perceptions regarding the need for vaccines may therefore become discordant with current immunization recommendations. Many parents need and want to know the rationale for the immunizations and to understand the risks. VARP's objective is to encourage

a shift from a strategy of "make it (immunization) obligatory" to a campaign of "make it real": make the need for the vaccines real, the name of the vaccine real, the disease the vaccine prevents real, the vaccine risk real, and the consequences of not vaccinating real. The goal is to have the parent become a partner in vaccine decisions and an active participant in the health of their child as well as in the public health of the community.

VARP scientists completed and published a variety of vaccine acceptance and risk perception studies in 2005, including:

- A survey of immunization attitudes and beliefs among parents
- Parent attitudes toward immunizations and healthcare providers: the role of information
- Parental vaccine beliefs and child's school type.
- Vaccine beliefs of parents who support and oppose mandatory vaccination.
- Factors influencing African-American mothers' concerns about immunization safety: a summary of focus group findings in Atlanta.

IMMUNIZATION SCIENCE

IMMUNIZATION SCIENTIFIC ACTIVITIES CONDUCTED or sponsored by NIP include conducting disease surveillance, investigating disease outbreaks, evaluating practices for immunization delivery, investigating improved technologies for immunization, and conducting social and behavioral research related to immunization. NIP also prepares immunization recommendations and communicates these findings to appropriate audiences. Immunization science addresses how we learn about immunization that helps protect everyone from vaccine-preventable diseases.

CONTINUING THE COMMITMENT TO IMMUNIZATION SCIENCE

Throughout NIP's history, practical, solution-oriented research has been on the rise. Today, more than 250 research projects are underway. Of these, most involve external partners. In collaboration with these partners, NIP is investigating:

- Impacts of newer vaccines, such as varicella and pneumococcal conjugate vaccine, in reducing and eliminating disease as coverage increases
- How well new vaccines work among special populations, such as children with asthma or sickle cell disease
- Better ways to protect infants and adults against diseases such as whooping cough
- The best way to design and conduct studies to uncover any rare adverse events that may follow immunization
- Monitoring the safety of several new vaccines
- Using computer models to predict the impact of vaccination in the event of a biological attack
- How vaccine shortages affect doctors' practices
- The reasons for racial or ethnic disparities in adult immunization coverage
- Improving the business processes for using computers to track children's vaccinations

- Finding the best ways to translate the success of vaccination to developing countries
- Promoting development of safer, needle-free immunization technologies, such as disposable-cartridge jet injectors and aerosolized vaccines, for mass vaccination campaigns and routine immunization
- Conducting clinical vaccine trials of needle-free jet injection to assess the safety, immunogenicity, user preferences, and feasibility of this method

VACCINE ECONOMIC STUDIES

In 2005, NIP continued its use of economic analyses to understand the complexity of the U.S. immunization system as well as immunization systems worldwide. Examples of studies related to the economic impact of immunization currently underway include:

Internal Studies

- Studying vaccine markets from development to commercialization
- Cost-benefit analyses of the routine childhood immunization schedule
- Cost estimation of mass vaccination clinics to identify efficient size
- Cost estimation of immunization registries to identify opportunities to improve efficiency

External Studies

- Joint Initiative in Vaccine Economics: estimation of the morbidity associated with varicella zoster; how states vaccination programs make vaccine provision decisions; economic study of global polio eradication: vaccine stockpiling and outbreak response modeling; estimation of the morbidity associated with adult influenza
- Studying the factors associated with uptake of clinical immunization standards
- Estimating the cost-effectiveness of childhood immunization strategies

NEW VACCINE SURVEILLANCE NETWORK

NIP's success in conducting practical, results-oriented research stems in part from continuing efforts to establish research partnerships and funding opportunities. With the right details in place—the personnel, facilities, and funding—research can be more timely, quickly answering pertinent questions for medical care providers and immunization policy makers. The New Vaccine Surveillance Network (NVSN), established in 1999, is one example of the many research efforts NIP sponsors. This network of sites investigates the impact of new vaccines and new vaccine policies on children who are hospitalized or are seen in emergency department outpatient settings. Along with other studies, NVSN is currently analyzing the burden of respiratory disease among young children. Researchers working in nine counties in three areas (Rochester, Cincinnati, and Nashville) discovered that children under age 5 are hospitalized for acute respiratory illness at the rate of 18 out of every 1,000 children, with respiratory syncytial virus (RSV) infections, parainfluenza, and influenza causing most of the disease. These data, supporting a high rate of hospitalization associated with influenza, were instrumental in a 2003 policy change to recommend flu vaccination routinely for all children age 6-23 months, effective Fall 2004. Vaccines for RSV and parainfluenza are in clinical trials. In the future, the NVSN will assess whether a reduction in the number and severity of acute respiratory illnesses occurs attributable to recommended vaccinations.

Immunization **AWARENESS**

COMMUNICATION, EDUCATION, COLLABORATION, AND PARTNERSHIP

IMMUNIZATION AWARENESS CAMPAIGNS

CHILDHOOD CAMPAIGNS

The National Immunization Program continues to promote awareness of the childhood immunization recommendations. In 2005, for the tenth consecutive year, NIP conducted a nationwide, public service and education campaign in Spanish and English to educate parents about the importance of childhood immunization. The campaign included television and radio public service announcements (PSAs) as well as print ads, posters, and media kits. In addition, the campaign promoted the CDC Information Contact Center, 800-CDC-INFO. Spokespersons for the Spanishlanguage campaign, Acting Assistant Secretary for Health and Human Services Rear Admiral Cristina V. Beato and CDC's José Cordero, promoted national childhood immunization through radio and television interviews on CNN Español and Telemundo. The campaign received more than 170 million media impressions from television, radio, and print—generating an estimated \$15 million in donated media.

In 2005, the eleventh annual National Infant Immunization Week (NIIW) was celebrated April 24–30. This event focuses on the importance of immunizing infants against vaccine-preventable diseases by age 2, and in 2005, NIIW coincided with Vaccination Week in the Americas (VWA). During NIIW, HHS and CDC joined the Pan American Health Organization (PAHO), the United States-Mexico Border Health Commission (USMBHC), and more than 35 nations in the Western Hemisphere to celebrate VWA, highlighting the need for routine vaccinations and promoting access to health services. Local organizations and communities across the country participated in NIIW-VWA, combining themes from PAHO ("Vaccination: an act of love") and CDC ("Love Them, Protect Them, Immunize Them.") in support of the continental childhood vaccination campaign.

Participants in NIIW included state and local health departments, healthcare providers, and other immunization partners. Public relations materials, planning tools, national childhood campaign materials, web banners and buttons, and logos were available from the NIIW website, www.cdc.gov/nip/events/niiw. NIP distributed English and Spanish-language materials to programs, partner agencies, and other organizations. The NIIW website received over 25,000 hits over a period of 10 weeks.

THE NATIONAL IMMUNIZATION PROGRAM'S communication, education, collaboration and partnership efforts help spread the word about immunization and educate the public, healthcare professionals, and all those involved in immunization efforts. NIP responds to requests from the public, the media, and healthcare professionals for information about vaccines and immunization. NIP also provides immunization education through course work, conferences, and information campaigns, and investigates the best way to reach its target audiences. Finally, NIP coordinates its communication and education activities with private

and public sector partners.

In the United States, NIP staff traveled to 14 cities in 9 states, including Newark, New Jersey, Fargo, North Dakota, and Washington, D.C., to participate in media events, grand rounds, provider education and training conferences, community forums, awards ceremonies, and other events promoting NIIW and VWA. Special events were also held in sister-city sites throughout the U.S.-Mexico border region.

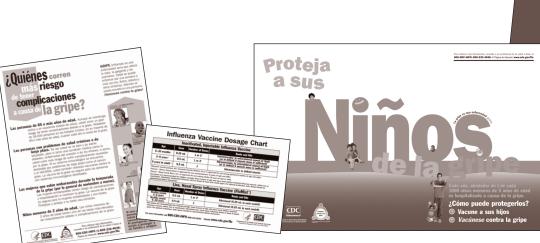
New Mexico and Louisiana served as national NIIW-VWA sites. A series of events were planned in both states including a kick-off event in Las Cruces, New Mexico, which brought together Deputy Surgeon General, Dr. Kenneth Moritsugu, New Mexico's First Lady, Barbara Richardson, and other health officials to support immunization efforts and celebrate New Mexico's success in increasing their infant immunization rates from 61% in 2000 to 77.9% in 2004. In Louisiana, Governor

Kathleen Babineaux Blanco declared April 24–30 as National Infant Immunization Awareness Week. More than 4,000 people were immunized during that week. New Orleans officials, including the mayor, participated in a press conference to kick off NIIW events in Louisiana and to highlight the importance of immunization. The U.S. events generated a great deal of publicity, providing opportunities to spread the message of the importance of childhood vaccination.

ANNUAL INFLUENZA CAMPAIGN

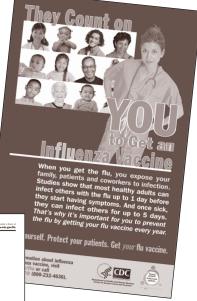
CDC's annual influenza vaccine promotion campaign was launched in 2005 in early September. Highlights included:

- Over 25 posters, flyers and brochures targeting parents, seniors, people with chronic health conditions, healthcare providers and the general public, available for download in Spanish and English from CDC's online Flu Gallery www.cdc.gov/flu/gallery
- Distribution of over 2,300 kits of sample educational materials to immunization program managers, city and county health officials, public health information officers and others
- Distribution of television and radio PSAs, radio media tours, and video and audio news packages targeting English and Spanish speakers
- \$2.3 million in donated media coverage and approximately 249.5 million audience impressions





immunize them.



Protect your child from 2 serious diseases... vaccinate on time every time.

COMMUNICATING ABOUT VACCINES AND IMMUNIZATION

RESPONDING TO THE MEDIA

Each year, NIP receives thousands of phone calls and e-mails from members of the media. Reporters seek information about the latest immunization recommendations, vaccine-related research, or the number of adults and children receiving a specific vaccine. In response to these requests, NIP activities include

- Posting the latest immunization-related information on the NIP website
- Releasing program updates and scientific announcements in the CDC Morbidity and Mortality Weekly Report (MMWR)
- Offering scientific and medical expertise for press conferences, briefings, and interviews
- Summarizing immunization recommendations, scientific findings, and immunization issues for quick reference

PROVIDING TECHNICAL ASSISTANCE TO HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

CDC Contact Center: CDC-INFO / 800-CDC-INFO (232-4636) / In English, En Español—24/7 / TTY: 888-232-6348

From March 1997 through early 2005 the National Immunization Information Hotline, operated by the American Social Health Association provided immunization information to both the public and providers. During this time Hotline staff answered almost 800,000 questions by telephone and email. In March 2005, immunization call center operations were integrated into the new consolidated CDC contact center—CDC-INFO. The contact center is operated by Pearson Government Services, primarily out of their operation center in Phoenix, Arizona. Since "going live" with immunization information, the call center has handled 426,198 contacts, of which 62,268 were immunization-related. The contact center operates 24 hours a day, 7 days a week.

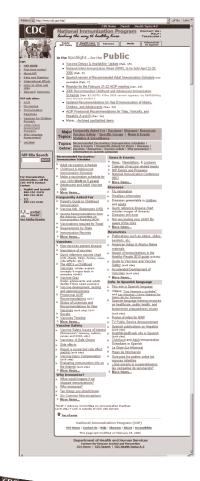
E-mail: NIPINFO@cdc.gov

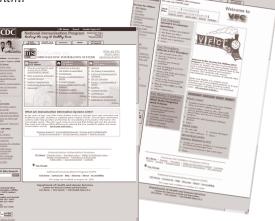
In 1995, the NIPINFO e-mail service was initiated to answer immunization questions from doctors, nurses, and other healthcare providers; today the service is used by the public as well as healthcare professionals. Most questions are answered within 24 hours. The annual volume of messages has increased from 2,084 in 1998 to 8,604 in 2005, an average of 39 per day. NIPINFO staff received an award at the 2005 NIP Annual Honor Awards Ceremony for their efforts to provide timely and accurate responses to e-mail questions.

NIP Website: www.cdc.gov/nip

In 2005, the NIP website continued to be upgraded and enhanced, and new ways to tap the potential for this powerful medium were explored. Notable additions and activities included:

- "Listening" on the Internet. The NIP website continues to be used by its public audience to send comments and suggestions about immunization policies. Online surveys and the "Contact Us" link are used to gather information about response to applications, news, and information on the website.
- Personalized Childhood Vaccine Schedule. One of the most popular additions to the NIP website in 2002, the "childhood scheduler" enables parents to create a personalized immunization schedule for their children; the program is updated promptly as immunization recommendations change.
- Vaccine Quiz for Adolescents and Adults. Added to the NIP website in 2004, the Vaccine Quiz is an interactive web page that helps adolescents and adults understand which vaccines they need. In 2005, the pertussis vaccine (Tdap) and the meningococcal vaccine (MCV4), newly recommended vaccines for adolescents and adults, were added to the Vaccine Quiz.
- Response to Hurricane Katrina. NIP worked with the Office of Preparedness and Emergency Response (OPER) to provide an online source of immunization information for health care workers, relief workers and residents of the Gulf Coast region affected by Hurricane Katrina.
- You Call the Shots. A web-based training course on immunization for healthcare providers was developed by NIP and launched in 2005. The web-based training modules currently available provide information on the general guidelines for immunizations as well as disease and vaccine specific information on polio, diphtheria, tetanus, and pertussis. Healthcare providers can visit www.cdc.gov/nip/ed/youcalltheshots.htm to complete the training modules. Immunization modules in development include Haemophilus influenzae type b (Hib), hepatitis A, hepatitis B, influenza, measles, mumps, and rubella (MMR), meningococcus, overview of bioterrorism, pneumococcus vaccine, vaccine administration practices, and varicella.
- ACIP Meetings. Attendees of ACIP meetings are now required to register online through a Web-based registration system developed and implemented by NIP. Those planning to attend ACIP meetings may register at www.cdc.gov/nip/ACIP/dates.htm.
- Immunization Information Systems. NIP's IIS website was redesigned in 2005 with more user-friendly navigation and information for three major audiences—parents, providers and state/city grantees. These audiences can find this information at www.cdc.gov/nip/registry/Default.htm.
- Storage & Handling Toolkit. This toolkit is a web-based, comprehensive resource offering detailed information on the proper storage and handling of vaccines, including recommendations and resources. The toolkit is available at www2a.cdc.gov/nip/isd/shtoolkit/splash.html.





COMMUNICATIONS RESEARCH

NATIONAL PRIMARY CARE PHYSICIAN SURVEY

To help physicians answer parents' questions and concerns about immunization, NIP is conducting a three-year survey of pediatricians and family physicians. This study, carried out by the Gallup Organization, identifies the questions parents ask about immunization and tracks how physicians answer these questions. In 2005, the third and final year of the study, researchers gathered data on vaccination attitudes and practices from 387 pediatricians and family physicians and their patients. Survey results will be used to analyze short-term childhood vaccination trends and to develop communication and educational materials for physicians and parents. Longitudinal analysis of vaccine usage and safety concerns are also underway.

PATIENT ENCOUNTER SURVEY

Data about patient encounters is collected annually by the Gallup Organization from a representative sample of providers and parents. Participants answer a series of questions about their attitudes, beliefs, practices, and concerns in relation to childhood vaccination. Researchers collect data about which vaccines are given late or are missed and why. This study uncovered significant differences in perceptions of vaccines issues; parents and physicians view them very differently. Results of the survey are scheduled to be presented at the 2006 National Immunization Conference, and analytical articles are in preparation.

QUALITATIVE COMMUNICATIONS RESEARCH

Avian Influenza

In August 2005, general public focus groups and physicians/healthcare provider indepth interviews on their attitudes, beliefs, and knowledge and about avian influenza (H5N1) and H5N1 vaccine were conducted. The focus groups, with 97 participants and 39 in-depth interviews, were held in New York City, Wichita, Kansas, Portland, Oregon, and San Francisco. The research indicated that:

- Awareness of avian influenza and the possibility of a pandemic was varied but was generally low.
- There was little sense of urgency among healthcare providers regarding a pandemic.
- The term "priority groups" when referring to persons who would receive avian influenza vaccination first had a strong negative connotation.
- Most physicians and healthcare providers reported that they would contact a local infectious disease specialist first for information about avian influenza.
- Many members of the public assumed that pandemic influenza vaccine allocation would be similar to seasonal influenza vaccine allocation.

Seasonal Influenza

Adults with Chronic Health Conditions

In May 2005, 30 focus groups were conducted with African-American, Caucasian, and Hispanic adults aged 50 to 64 at high risk for complications from influenza to assess the effectiveness of CDC's outreach materials. The research indicated that:

- Participants understand that seniors and infants should be immunized for influenza.
- Older adults tend to believe that certain types of people such as seniors and infants should be immunized because they are at greater risk of getting influenza and tend to not recognize that such people are actually at greater risk of suffering complications from influenza.
- A number of concerns regarding the efficacy and safety of influenza vaccine persist.
- Older adults with chronic conditions need outreach materials that include a basic definition of chronic conditions, include examples of chronic conditions, and state that people with chronic conditions are at greater risk for suffering from complications of influenza and should thus receive influenza vaccinations annually.

Nurse Study

In June 2005, 45 in-depth interviews were conducted with African-American and Caucasian nurses to assess the effectiveness of CDC's outreach materials. The research indicated that:

- Nurses express many of the same concerns regarding the efficacy and safety of the influenza vaccine as do members of the general public. Unlike the general public, however, nurses believe that being regularly exposed to illness in their professional lives increases their resistance to influenza.
- Many nurses said they were not vaccinated against influenza in the 2004-2005 influenza season. Some of these nurses indicated they "stepped aside" so that others could be vaccinated instead. In addition, nurses tended to regard vaccination as a way to prevent getting influenza from a patient, yet few realized vaccination could help them prevent spreading influenza to their patients.
- To reach nurses who are reluctant to be vaccinated, outreach items that include highly detailed information should be developed and widely distributed. For nurses who are amenable to being vaccinated, less detailed items, such as posters, are effective behavioral triggers.

"Non-Doers" Aged 50 and Older

In July 2005, twelve focus groups were conducted with African-American, Caucasian, and Hispanic adults age 50 and older who declined to receive an influenza vaccine (designated in the study as "non-doers") during the previous two influenza seasons—in spite of being part of a group for whom the vaccine is recommended. The purpose of the study was to assess the perceptions, opinions, beliefs and attitudes held by these groups about influenza disease and the vaccine, and to test messages and materials. The research indicted:

- Many non-doers see getting a flu shot as a gamble, because they reported believing the vaccine does not always seem to protect against the illness, and might even cause the illness.
- Since many participants have never been seriously ill with influenza in the past, they do not perceive this as a serious threat to their health or lifestyle.

- Respondents want a credible explanation for why the vaccine cannot cause influenza, when they see people becoming ill after receiving it. The blanket denial that the "shot cannot cause the flu" makes it appear that healthcare authorities are lying.
- Focus group participants found it useful to receive simple yet somewhat detailed information that described how vaccines work, how they protect against virus strains, how flu vaccines are more pure than they used to be and therefore cause fewer systemic side effects, and how scientists measure vaccine efficacy.
- Some members of this group do not realize the vaccine is recommended for them and simply need this information.
- Some people will not be convinced to participate in this health behavior no matter what is said to them; however, a certain number of non-doers can be convinced to change their minds.

OTHER AVENUES FOR EDUCATION AND COMMUNICATION

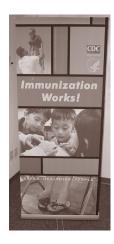
NATIONAL IMMUNIZATION PROGRAM TRAVELING EXHIBIT

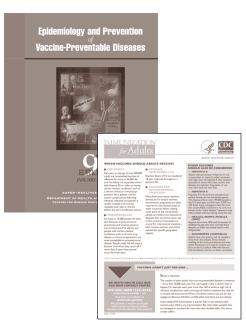
NIP exhibits at national and regional conferences to inform healthcare providers and consumers about immunization recommendations, policies, resources, and scientific findings. Through this exhibit, NIP promotes its website, publications, training programs, and many other immunization resources. The exhibit offers brochures about immunization topics, CD-ROMs with current immunization information, and pocket-sized, laminated immunization schedules. In 2005, NIP's exhibit was displayed at 18 meetings and conferences, sometimes in conjunction with exhibits from NCID and NCHSTP. Among the larger conferences were the National Association of School Nurses, the National Medical Association, and the American Academy of Family Physicians.

PRINT AND ELECTRONIC PUBLICATIONS

The National Immunization Program publishes immunization materials in both print and electronic formats. Materials can be requested by phone, fax, mail, and e-mail, and many can be accessed directly from the NIP website. Many materials are also available through the NIP online ordering system at www.cdc.gov/nip/publications. Materials include:

- Fact sheets, brochures, and question-and-answer documents on subjects such as immunization recommendations, vaccine safety, registries, and the VFC program
- Reference books and materials, such as the "Surveillance of Vaccine-Preventable Diseases" manual and the *Epidemiology and Prevention of Vaccine-Preventable Diseases* text (better known as the "Pink Book"). A major public health immunization reference, the Pink Book is available in an annually updated print version. To date, 46,468 copies of the 8th edition of the Pink Book have been purchased through the Public Health Foundation (PHF) The electronic version, available for download from the NIP website, is updated continuously. The 9th edition was released February 2006.

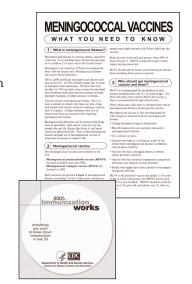




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- Patient education materials on current topics, including vaccine information statements (VISs), Parents' Guide to Childhood Immunization, and a variety of materials that address vaccine recommendations, vaccine safety issues, and childhood and adult immunizations concerns
- VHS videotapes and DVDs of immunization-related training for healthcare providers
- Computer-based and web-based, self-study courses
- CD-ROMs for healthcare provider education.

Each year, the NIP Resource and Information Center distributes a wide variety of publications and resources. Highlights for 2005 include the distribution of 413,500 printed items, 32,500 CD-ROMs, and 4,600 VHS videotapes and DVDs. Particularly popular were the Childhood/Adolescent and Adult Immunization Schedules (64,000), Immunization Works CD (22,000 copies), and the VIS Booklet (for providers—33,000 copies).





HEALTHCARE PROVIDER EDUCATION

The National Immunization Program offers healthcare provider training and education through a variety of media, including self-study and instructor-led satellite, Internet, and land-based courses, speaker presentations, and NetConferences. In addition, NIP presents immunization modules in medical residency programs and medical and nursing school curricula.

In 2005, NIP staff delivered 115 in-person presentations in 31 states and the District of Columbia to 14,362 healthcare professionals. Other training included three land-based courses, six satellite broadcasts, four NetConferences (webcasts with telephone conferencing) and three web-based modules.

Most NIP training and education activities offer continuing education (CE) credit. Types of credit awarded include Continuing Medical Education (CME), Continuing Nursing Education (CNE), Continuing Education Units (CEU), Continuing Pharmacy Education (CPE), and Continuing Education Contact Hours (CECH) for health educators. In 2005, over 22,000 healthcare providers were awarded CE credit for participation in NIP programs. NIP also sponsors conferences and meetings to support immunization education for healthcare professionals.



NIP-SPONSORED EVENTS IN HEALTHCARE EDUCATION



NATIONAL IMMUNIZATION CONFERENCE

The thirty-ninth National Immunization Conference was held in Washington, D.C. at the Washington Hilton Hotel on March 21–24, 2005. Co-sponsors of the Conference were the Task Force for Child Survival and Development, Centers for Medicare and Medicaid Services (CMS), and the CDC Foundation. The National Foundation for Infectious Diseases (NFID) was host of the separate but concurrent vendor exhibit. The Conference was attended by 1,593 persons from all 50 states, some U.S. territories, and several other countries.

For the first time, the conference was run on a track-based system. Participants could choose to attend workshops in one of six tracks: Adult Immunization, Epidemiology, Health Communications, Immunization Registries, Programmatic Issues, and Vaccine Safety. In all, 12 workshop sessions (a total of 67 workshops) and three joint plenary sessions were offered. A highlight was a large plenary session celebrating the 50th anniversary of the introduction of polio vaccine.

The exhibit hall contained 110 posters and 24 not-for-profit exhibits. Popular features of the Conference were two well-attended immunization question-and-answer sessions hosted by EIPB's training team, and Lunch Rounds, which were attended by almost 350 persons. A total of 443 people received continuing education credit in the form of physician and non-physician CME, CNE, CEU, CPE, and CECH for health educators.

EDUCATION SUCCESS: NETCONFERENCE

NIP has adopted a new technology to enhance audience participation and attract new audiences for immunization education programs. This technology, "NetConference," combines live, online visual presentations with simultaneous audio transmission through a telephone line. The one-hour "seminars" include live question-and-answer sessions. Audience members watch the presentations on computer screens, listen over a telephone line, and call in questions and comments. The presentations are scheduled four times each year.

In 2005, NIP staff produced four "Current Issues in Immunization" NetConferences covering the topics of varicella case-based reporting, meningococcal and influenza vaccine, new ACIP recommendations on varicella and Tdap, and seasonal influenza information. NIP also supported four additional NetConferences. In 2005, over 3,400 participants have registered for NetConference attendance, and 949 participants received continuing education credit.

NEW TRAINING & EDUCATION PRODUCTS AND IMMUNIZATION RESOURCES

IMMUNIZATION: YOU CALL THE SHOTS

In 2005, NIP launched *Immunization: You Call the Shots*, an interactive, web-based training course consisting of a series of modules that cover recommendations on vaccine use, proper vaccine administration practices, and vaccine storage and handling guidance. The modules include self-tests to assess learning and provide extra learning opportunities, links to resource materials, and an extensive glossary. The modules developed so far are "Understanding the Basics: General Recommendations on Immunization," "Diphtheria, Tetanus, and Pertussis," and "Polio." This self-study course is intended for introductory training of healthcare professionals who provide immunizations and can serve as a reference or refresher for all immunization providers. Continuing education credits are offered. The course is available free of charge on the NIP website at: www.cdc.gov/nip/ed/youcalltheshots.htm.. https://www.cdc.gov/nip/ed/youcalltheshots.htm.. https://www.cdc.gov/nip/ed/youc



EDUCATING PHYSICIANS IN THEIR COMMUNITIES

NIP staff partnered with the Georgia Chapter of the American Academy of Pediatrics to provide peer-to-peer education for immunization providers. The Educating Physicians in their Communities (EPIC) program addresses standards number 8 in Standards for Adult Immunization Practices and number 10 in Standards for Child and Adolescent Immunization Practices regarding provider training and education. EPIC brings immunization education to the practice setting.

VACCINE STORAGE AND HANDLING TOOLKIT

In 2005, NIP introduced Web-based and CD-ROM versions of a new resource for healthcare personnel who provide immunization services. The Vaccine Storage and Handling Toolkit is a comprehensive resource that provides detailed information on the proper storage and handling of vaccines. The Toolkit covers such topics as maintaining the cold chain, proper equipment and temperature monitoring and vaccine preparation and disposal.

ESTABLISHING PARTNERSHIPS AND FOSTERING COLLABORATION

NIP works with local, state, national, and international partner organizations to increase awareness of immunization recommendations, foster the development and implementation of effective immunization programs, and achieve high immunization coverage levels. Effective strategies for delivering and evaluating immunization services include use of immunization information systems (including immunization registries), regular audits of immunization records, and collaborating to reach underimmunized populations.

NIP also develops partnerships with community organizations and private healthcare providers to increase awareness of immunization recommendations and the use of "best practices."

FEDERAL, STATE, AND COMMUNITY SUPPORT

NIP brings together many partners to coordinate vaccine policies and initiatives. Achieving our nation's immunization goals depends upon collaboration among professional organizations, state and federal public health agencies, vaccine manufacturers, and other healthcare provider and community partners. These joint efforts span each phase of vaccine development and delivery.

IMMUNIZATION GRANT FUNDS

Federal funding for the Immunization Grant Program (also called the "Section 317 grant program") began in 1963. In 2005, NIP administered over \$400.7 million in federal grants to 64 state, local, and territorial public health agencies for program operations and purchase of vaccines not covered by the Vaccines for Children Program (VFC). An additional \$1.37 billion was provided to the state, local, and territorial public health agencies through the VFC program. Under the VFC program, publicly purchased vaccines are provided to public and private healthcare providers for administration to eligible children at no charge. State, territorial, and local immunization programs use these federal funds to purchase vaccines. Section 317 funds also help to maintain an immunization infrastructure to assure service delivery, conduct surveillance of vaccine coverage and safety, and sustain and improve vaccination levels. Immunization grantees receive technical assistance through site visits and routine communications from program consultants at NIP.

COOPERATIVE AGREEMENTS

NIP collaborates with private provider organizations, national minority organizations, and coalition groups to promote immunization. Partnerships with these groups are instrumental in educating healthcare providers and the public about immunization recommendations and in addressing vaccine safety concerns. Funding to national minority organizations and coalition groups has enhanced understanding of specific needs and has enabled the development of appropriate messages for special populations, including those at high risk for vaccine-preventable diseases. Through healthcare provider cooperative agreements, NIP has increased healthcare provider education and standardized immunization policies and practices.

One very successful cooperative agreement is with the American Pharmacists Association (APhA). As the largest national association of pharmacists in the country, APhA serves more than 50,000 practicing pharmacists, pharmacy students, and others. Through this partnership, APhA has promoted immunization messages and materials to member pharmacists nationwide and collaborated with physicians and others to increase the public's access to immunizations. In addition, the partnership has helped NIP respond to new immunization issues as they emerge. Amid concerns about the influenza vaccine supply situation, NIP worked with APhA to survey pharmacists across the country about their influenza vaccine supply. The survey results will help NIP plan for next year's influenza season.

Another successful partnership is with the American Academy of Pediatrics (AAP). The AAP has used NIP funding to support its Childhood Immunization

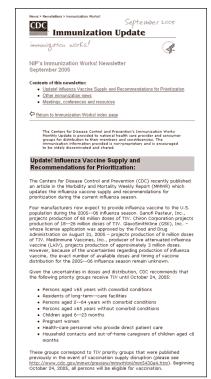
Support Program (CISP). This program works to improve the immunization delivery system for children across the nation. Through web-based resources, training modules, newsletters, meetings and events, the CISP program works to inform pediatricians across the country about the latest immunization practices and recommendations. AAP is currently developing a training module in immunization which will provide assistance for improvement of pediatric vaccine administration. Because pediatricians provide the vast majority of childhood immunizations, the partnership between CDC and AAP is critical in ensuring that all children are immunized on time.

PARTNER COMMUNICATION PROGRAM

NIP offers the Partner Communication Program (PCP) to communicate with health departments and national organizations about issues that affect immunization in the United States. Currently, the PCP comprises 131 partner organizations representing physicians, nurses, pharmacists and other healthcare professionals; policy makers; and minority groups. PCP supports NIP's *Immunization Works* monthly e-letter and the *Emergency Communication Program*.

Immunization Works provides information about new immunization advances, recommendations and resources. National organizations that receive Immunization Works can include information from the e-letter in their own electronic and print publications, greatly expanding its reach. The e-letter can be accessed from the NIP website at www.cdc.gov/nip/news/newsltrs/imwrks/imwrks.htm.

The Emergency Communication Program enables rapid communication about issues that might have an immediate impact on healthcare professionals and those they serve—issues like vaccine shortages and disease outbreaks. News and information about vaccine shortages, disease outbreaks, storage and handling and other urgent situations are distributed through the Emergency Communications Program.



ANTICIPATING THE EXTRAORDINARY

OFFICE OF PREPAREDNESS AND EMERGENCY RESPONSE

CRISES AND DISASTERS from influenza vaccine shortages, tsunamis, hurricanes, earthquakes and floods, to emerging threats such as avian influenza marked 2005. The year began with one of the world's worst disasters, the South Asian tsunami, that killed more than 280,000 people and left millions more without homes and basic necessities. In late August, Katrina, one of three category-five hurricanes, devastated New Orleans, killing 1,300 people and displacing millions throughout the southern states. Hurricane Rita struck within a few weeks, sending oil prices soaring, and Wilma followed in October. Soon after, a 7.6-magnitude earthquake struck in Northern Pakistan, for which the death toll passed 80,000 and more than three million were left without homes.

HURRICANE RESPONSE EFFORTS

Before Hurricane Katrina made landfall in August, the Office of Preparedness and Emergency Response (OPER) began working in the Director's Emergency Operations Center (DEOC) in anticipation of several issues that were certain to arise in the aftermath of the storm. OPER staff assisted in the initial recruitment of CDC's public health response teams, who could initially deploy during the response, and over 70 people from NIP were deployed on missions to the affected region or to lead and support teams in the DEOC. OPER staff played a key role in helping to lead the CDC-wide deployment efforts in response to Hurricanes Katrina, Rita, and Wilma. Many of the deployed staff from NIP headquarters conducted needs assessments in states affected directly or indirectly by the hurricanes. In discussions with those states, NIP staff helped to determine what the states needed to keep immunization programs going, especially in terms of their vaccine needs.

OPER coordinated the issuance of interim vaccination recommendations for emergency workers deployed to areas impacted by Hurricane Katrina as well as displaced persons from this region. The focus of the recommendations for displaced persons was two-fold: one, to ensure that children, adolescents, and adults are protected against vaccine-preventable disease in accordance with current recommendations, and two, to reduce the likelihood of outbreaks of vaccine-preventable diseases in large crowded group settings. Along with these recommendations, NIP worked with FDA to assess the supply of all vaccines recommended for workers and for those in shelters, including what the manufacturers had in stock, what was available in CDC's stockpile, and what could be identified in state inventories. Manufacturers also donated vaccines directly to states or private organizations, and NIP monitored

the magnitude of those donations. OPER, in collaboration with NIP's Immunization Services Division, also coordinated the purchase of vaccine supplies in accordance with the interim recommendations for the states of Louisiana and Mississippi.

In addition to the doses purchased, the Texas state health department used vaccines on hand to begin vaccination of sheltered persons in Houston, Dallas, and San Antonio. When these vaccine supplies were exhausted, NIP helped to arrange for other states not impacted by the hurricane to contribute vaccine resources—more than \$6 million worth—to support ongoing vaccination activities. Texas then had adequate supplies of vaccine on hand to vaccinate the remaining displaced persons.

Through the end of 2005, NIP remained in frequent contact with the state immunization programs which oversee or manage vaccination initiatives among displaced persons and emergency first responders.

IMMUNIZATION INFORMATION SYSTEMS HELP CHILDREN AVOID EXTRA IMMUNIZATIONS

In Louisiana, Mississippi, and Alabama, many people who had to evacuate because of Hurricane Katrina lost not only homes and possessions but personal records such as their children's immunization records. Existing immunization information systems made it possible for states to locate children's records to determine immunization status prior to school enrollment. In Louisiana alone, CDC estimated that as early as October 2005, more than 20,000 queries were made to the Louisiana Immunization Network for Kids Statewide (LINKS) regarding vaccination histories for children who were evacuated. LINKS remains functional because a backup system located in Baton Rouge has been operational since Katrina struck.

An Alabama Department of Public Health professional spent the day in an evacuation center. When she asked one mother with seven children whether she had any immunization records, the mother said she had nothing. Using the LINKS system, the public health professional found records on six of the seven children. The mother exclaimed, "We have proof that we are real people!"

Thousands of young evacuees throughout the United States have benefited from LINKS by gaining access to their immunization records electronically. Although special provisions were made to accept students without proof of immunization into their new schools, having an immunization record provides extra assurance that no delays will occur, and no immunizations will be repeated unnecessarily. CDC recommends that children be vaccinated again if records do not exist. CDC estimates that 75% of the immunization history queries made to LINKS have been from Texas, particularly from the Houston area.

For health professionals only, several means were made available to access immunization history data from LINKS, including using Health Level 7 (HL7) messaging or just "view only" access. HL7 enables not only access to information but also the ability to input information. For example, if a provider administers a vaccination to a child who was displaced, they may input this information into LINKS directly from their location, and the immunization record stays up-to-date. As of



Vaccinating local health workers in Gulfport, Mississippi following Hurricane Katrina

early October 2005, eight states and the city of Houston had HL7 direct access to LINKS. "View-only" enables a provider to access LINKS and to view the immunization history from their location. A total of 43 states, Washington, D.C., and 10 cities have "view-only" access to LINKS.

These connections established by NIP immunization information systems enabled many immunization histories to be retrieved thereby reducing or eliminating the need for costly re-vaccination of Hurricane Katrina displaced children.

PANDEMIC INFLUENZA PREPAREDNESS

ONE OF THE MOST IMPORTANT PUBLIC HEALTH ISSUES our nation and the world faces is the threat of pandemic influenza. The ongoing outbreaks of avian influenza in birds have the potential to turn into a human influenza pandemic that could have significant global health, economic, and social consequences. To date, outbreaks of the H5N1 strain of avian influenza have been confirmed among birds in Cambodia, China, Croatia, Indonesia, Kazakhstan, Laos, Mongolia, Romania, Russia, Thailand, Turkey, and Vietnam. Japan, Malaysia, and South Korea have also experienced outbreaks in the past. More than 60 deaths out of over 120 human cases of the disease have been confirmed in Cambodia, Indonesia, Thailand and Vietnam.

NIP's OPER has been actively engaged in the pandemic influenza planning efforts. NIP staff also contributed to the preparation of the draft National Pandemic Influenza Preparedness and Response Plan, which outlines a coordinated national strategy for dealing with an influenza pandemic. Released in August 2004 and updated in November 2005, the plan provides an overview of key issues involved in facing such a pandemic and outlines actions that should be taken at the national, state, and local levels before and during a pandemic. The plan also includes information for health departments and private sector organizations for use at the local level. The HHS Pandemic Influenza Plan can be viewed at www.hhs.gov/pandemicflu/plan/.

Working with the National Center for Infectious Diseases (NCID) and the Office on Terrorism Preparedness and Emergency Response, NIP has also initiated a

series of four regional meetings about pandemic influenza planning. Regional meetings, were in Chicago, Denver, Boston, and Atlanta during 2005, were instrumental in bringing state and federal expertise together to discuss planning challenges and identify innovative approaches to solving common problems concerning pandemic influenza. They included presentations by both CDC staff and state presenters, as well as discussion sessions around selected topics, and provided information to help states move forward in developing their pandemic preparedness plans.

The Public Engagement Pilot Project on Pandemic Influenza to discuss and rank goals for a pandemic influenza vaccination program and to pilot test a new model for engaging citizens on vaccine related policy decisions



In preparation for national pandemic influenza exercises held in 2005 (Pinnacle in June, Pandemic Fury in December), OPER coordinated with subject matter experts from NIP, the National Center for Infectious Diseases, and the Strategic National Stockpile to prepare background material and guidance for the exercise participants.

PUBLIC ENGAGEMENT PILOT PROJECT ON PANDEMIC INFLUENZA

The Public Engagement Pilot Project on Pandemic Influenza (PEPPPI) was initiated in July 2005 to discuss and rank goals for a pandemic influenza vaccination program and to pilot test a new model for engaging citizens on vaccine related policy decisions (The Vaccine Policy Analysis CollaborativE, VPACE). The Pilot Project was sponsored by a network of interested organizations including NIP. To conduct this public consultation, the sponsors engaged stakeholders from various organizations with an interest in pandemic influenza (the National Stakeholder Group), and individual citizens at large from the four principal regions of the United States. The anticipated major benefits from this public consultation were the development of an improved plan to combat pandemic influenza and one more likely to gain public support, and a demonstration that citizens can be productively engaged in informing vaccine related policy decisions.

PEPPPI was carried out in five phases—two day-and-a-half dialogue and deliberation meetings with approximately 50 national stakeholders and consultants, a day-long consultation with over 100 citizens at large in Atlanta which took place inbetween the two stakeholder meetings, and three half-day sessions conducted with approximately 150 citizens at large in Massachusetts, Nebraska, and Oregon where citizens were shown the results of the earlier deliberations and asked for their feedback.

Both citizens at large and the National Stakeholder Group decided—with a very high level of agreement—that assuring the functioning of society should be the first immunization goal followed in importance by reducing the individual deaths and hospitalizations due to influenza (i.e., protecting those who are most vulnerable and at risk). Because of the still high importance of the second goal, the groups added that the first goal should be achieved using the minimum number of vaccine doses required to assure that function. This would allow the remaining doses to be used as soon as possible for those at highest risk of death or hospitalization. There was little support for other suggested goals to vaccinate young people first or to use a lottery system or a first-come, first-served approach as top priorities. The groups also defined the federal government's role as providing broad guidance with responsibility for more specific interpretation and implementation remaining with state and local health authorities. Both the public participants in this pilot project and the expert advisory bodies which deliberated separately, ACIP and NVAC, chose protecting society's caretakers and persons at high risk among their top priorities. However, the weight attached by the citizens at large and the National Stakeholder Group to "Assuring the Functioning of Society" appeared to be greater than the weight placed on this goal by the expert advisory bodies. Their joint subcommittee placed higher priority on protecting high risk persons and lower priority on most of the categories of persons responsible for assuring the functioning of society.

This pilot project illustrated to the vaccine community that a diverse group of stakeholders and citizens at large can be recruited to learn about a technical subject, interact respectfully, and reach a productive outcome on an important policy question. Preliminary results from the independent evaluation of all the sessions conducted by the University of Nebraska reaffirmed this conclusion. Furthermore, the corroboration of the results of the deliberations from the four sessions involving the general public in disparate regions of the country, as well as with the National Stakeholder Group meeting in Washington D.C., gives additional weight to the recommendations. Recognition of the importance and utility of these findings was made evident in the HHS Pandemic Influenza Plan released in early November 2005, which described the agency's consideration of the priorities that emerged from the PEPPPI project. More public discussion of a similar type was called for in the HHS plan. The complete PEPPPI report is available at www.keystone.org/spp/documents/FINALREPORT PEPPPI DEC 2005.pdf.

ACCOMPLISHMENTS IN SMALLPOX ACTIVITIES

SMALLPOX VACCINE SAFETY

Several publications have been completed describing some of the surveillance results for adverse events following smallpox vaccination. Other manuscripts describing surveillance activities are in press.

Adverse Events Associated with Smallpox Vaccination in the United States, January-October 2003 describes the components and findings of the comprehensive HHS smallpox vaccine safety monitoring and response system. The rigorous smallpox vaccine safety screening efforts and educational programs, along with an older vaccinee population likely contributed to low rates of preventable life-threatening adverse reactions. Cardiac adverse events—an unexpected finding—and other rare or clinically significant events were detected by rapid review of VAERS data and intensive clinical investigation.

Superinfection Following Smallpox Vaccination (Vaccinia), United States: Surveillance January 2003 through January 2004 reports that this adverse event was rare during the HHS vaccination program. Many reported superinfection cases were probably large normal smallpox vaccine reactions (robust takes). The case definition for superinfection following smallpox vaccination is included in this publication.

Generalized Vaccinia, Progressive Vaccinia, and Eczema Vaccinatum Are Rare following Smallpox Vaccination (Vaccinia): United States Surveillance, 2003 provides standard case definitions for these three adverse reactions following smallpox vaccination. Two of 29 (7%) reports of possible generalized vaccinia among nearly 38,000 vaccinees met the case definition. None of the three possible eczema vaccinatum and seven possible progressive vaccinia cases met the case definitions. The publication concludes that careful prevaccination screening probably contributed to the low incidence of these adverse reactions.

SMALLPOX DISEASE SURVEILLANCE

The performance of the CDC algorithm for specificity and misclassification of highrisk patients for smallpox was assessed in a rash algorithm study. Nearly 27,000 patients with rash were screened in emergency departments or inpatient units of hospitals. Less than 1% of the patients had an acute, generalized vesicular or pustular rash and they were rarely (1.2 per 1000 admissions) admitted to emergency departments and inpatient units. The CDC algorithm correctly classified these patients as low risk for smallpox.

The CDC Smallpox Response Plan and Guidelines – Guide A (Epidemiologic Preparedness and Response) was completed and revised by NIP. Further responsibility for Guide A will reside with NCID's Bioterrorism Preparedness and Response Program.

EMERGENCY RESPONSE SEMINAR

NIP'S OFFICE OF PREPAREDNESS AND EMERGENCY RESPONSE (OPER), in collaboration with the Coordinating Office for Terrorism Preparedness and Emergency Response, hosted a seminar in August 2005 to provide NIP employees a basic understanding of emergency response for public health incidents. This event helped to ensure that future response activities are successfully coordinated. A key objective of the seminar was to provide NIP staff who may become involved in large-scale emergencies with an understanding of how responses are structured using the Incident Command System (ICS) and what an individual's role(s) may be during a particular event. The seminar also provided a summary of the policies and plans are that guide the federal government's management of domestic incidents (e.g. the National Response Plan, the National Incident Management System, etc.). During the response to the hurricanes in 2005, many attendees were able to see how CDC implemented the ICS and how its operations were conducted under the National Response Plan.

MASS VACCINATION CLINIC EXERCISES

MASS VACCINATION IS A KEY PUBLIC HEALTH RESPONSE to a naturally occurring outbreak or bioterrorist incident, and the 2003 Smallpox Vaccination Preparedness Plan required state and local health authorities to begin preparing for vaccination of large groups of people against smallpox. As a result, state and local health authorities have conducted mass vaccination clinic exercises to practice their ability to vaccinate entire populations in a limited amount of time.

NIP's OPER is systematically collecting and compiling information from the state and local health departments which have conducted these mass vaccination clinic exercises to identify lessons learned and best practices. This project will categorize and highlight the aspects of mass vaccination clinics that are timely, accessible, and efficient, and which will enable CDC to better understand current mass vaccination preparedness activities at the state and local level. The information gathered from this project may be used by CDC to develop general recommendations and, eventually, national guidelines for mass vaccination clinics occurring at the state and local level.

San Antonio – Over 70 NIP people were deployed to missions here and at other hurricane relief centers along the Gulf Coast.





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CALENDAR OF EVENTS

Phacilitate North American Vaccine Forum January 30–February 1 Baltimore Marriott Waterfront Baltimore, Maryland www.phacilitate.co.uk/pages/baltimore_vac/

Epidemiology and Prevention of Vaccine-Preventable Diseases (4 Parts) February 9, 16, 23, March 2 (Thursdays) Satellite Broadcast www.phppo.cdc.gov/phtn/webcast/epv06/default.asp

40th National Immunization Conference March 6–9 Omni Hotel at CNN Center Atlanta, Georgia 404-639-8225 www.cdc.gov/nip/nic/

5th Annual National Initiative for Children's Healthcare Quality Forum (NICHQ) March 16–18 Royal Pacific Resort, Orlando, Florida 866-787-0832 www.nichg.org

International Conference on Emerging Infectious Diseases March 19–22 Marriott Marquis, Atlanta, Georgia www.iceid.org/abstractsubmission.htm

Epidemiology and Prevention of Vaccine-Preventable Diseases

April 11–12 Indianapolis, Indiana Contact Beverly Sheets 317.501.5722 or hepbbev@aol.com www.in.gov/isdh/programs/immunization/ immunization.htm

9th Annual Conference on Vaccine Research May 8–10 Baltimore Marriott Inner Harbor Hotel Baltimore, Maryland vaccine@nfid.org, 301.656.0003 ext. 19, fax: 301.907.0878 www.nfid.org/conferences/vaccine06/

National Rural Health Association (NRHA) May 15–19 Reno, Nevada 816-756-3140 www.nrharural.org/conferences/sub/calendar.html

American College of Nurse Midwives May 26–June 1 Grand America Hotel, Lake City, Utah 240-485-1800 www.midwife.org/news.cfm?id=209 American College of Preventive Medicine (ACPM)
February 22–26

February 22–26 John Ascuaga's Nuggett Resort Reno/Tahoe, Nevada www.acpm.org/comm.htm www.preventivemedicine2006.org/planning. htm

Bird Flu Summit February 27–28 Washington, DC

World Vaccine Congress Washington 2006 March 20–23 Four Seasons Hotel, Washington, DC +44 (0) 207 539 4336 julie.phillips@terrapinn.com www.lifescienceworld.com/2006/wvcm_CA

National Association of Pediatric Nurse Practitioners (NAPNAP) March 30–April 2 Marriott Wardman Park Hotel Washington, DC 856-857-9700 www.napnap.org/index.cfm?page=12&sec=97

National Infant Immunization Week (NIIW) April 22–29 www.cdc.gov/nip/events/niiw/default.htm

55th Annual Epidemic Intelligence Service (EIS) Conference
April 24–28
Sheraton Midtown Atlanta Hotel
at Colony Square, Atlanta, Georgia
Contact Erica Lowe
404-498-6110 or Elowe@cdc.gov
www.cdc.gov/eis/conference/conference.htm

34th Annual Physician Assistants Conference — American Academy of Physician Assistants (AAPA) May 27-June 1 Moscone Convention Center San Francisco, California 703-836-2272 www.aapa.org/annual-conf/index.html

Global Health Council's 33rd Annual International Conference May 30–June 2 Washington, DC www.globalhealth.org/conference/ 12th International Congress on Infectious Diseases June 15–18 Lisbon, Portugal 617-277-0551 or info@isid.org www.isid.org/12th_icid 38th Annual National Association of School Nurses (NASN) Conference June 30–July1 New York Marriott Marquis Hotel

New York, New York

www.nasn.org/Default.aspx?tabid=109

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National Association of County and City Health Official's (NACCHO) Annual Conference

July 26–28 Marriott San Antonio Rivercenter Hotel San Antonio, Texas info@naccho.org www.naccho.org/conferences/NACCHOannual06/

National Medical Association (NMA) 2006 Annual Convention and Scientific Assembly August 5–10 Dallas, Texas 202-347-1895

www.nmanet.org/Conferences_National.htm

7th National Conference on Immunization Coalitions

August 9–11
Hyatt Regency–Denver at Colorado
Convention Center, Denver, Colorado
Contact Roberta Smith
Colorado Influenza and Pneumococcal Alert
Coalition, Adult Immunizations:
303.692.2332 or roberta.smith@state.co.us
www.seeuthere.com/rsvp/invitation/invitation.
asp?id=/m2c666-455170415278

National Black Nurses Association 33rd Annual Institute and Conference August 9–13 Westin Diplomat Resort & Spa Fort Lauderdale, Florida 301-589-3223 www.nbna.org/conferences/conf06/conf06.htm

2nd International Conference — Modern Vaccines Adjuvants & Delivery Systems (MVADS 2006)

September 12 The Royal Society of Medicine London, United Kingdom www.meetingsmanagement.com/mvads_2006/

Association of State and Territorial Health Officials (ASTHO) 2006 Annual Meeting September 12–15 Hyatt Regency, Atlanta, Georgia www.astho.org/pubs/2006AMlogistics.pdf

National Adult Immunization Awareness Week September 24–30 Nationwide

www.cdc.gov/nip/events/naiaw/default.html

80th Annual School Health Conference of the American School Health Association October 11-15 St. Louis, Missouri mbramsier@ashaweb.org

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Immunization PUBLICATIONS

NATIONAL IMMUNIZATION PROGRAM PUBLICATIONS – 2005

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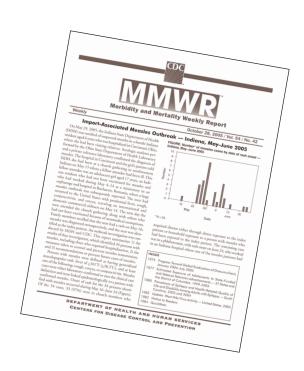
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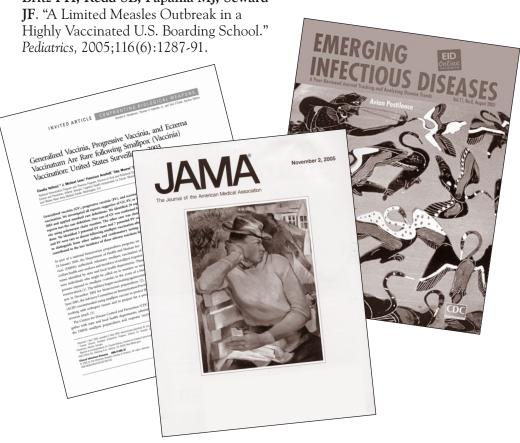
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PEER-REVIEWED

VACCINE SAFETY

RESEARCH

ARTICLES

ANNEX

CHILDHOOD AND ADOLESCENT SCHEDULE FOOTNOTES

- 1. Hepatitis B vaccine (HepB). AT BIRTH: All newborns should receive monovalent HepB soon after birth and before hospital discharge. Infants born to mothers who are HBsAg-positive should receive HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. Infants born to mothers whose HBsAg status is unknown should receive HepB within 12 hours of birth. The mother should have blood drawn as soon as possible to determine her HBsAg status; if HBsAq-positive, the infant should receive HBIG as soon as possible (no later than age 1 week). For infants born to HBsAgnegative mothers, the birth dose can be delayed in rare circumstances but only if a physician's order to withhold the vaccine and a copy of the mother's original HBsAg-negative laboratory report are documented in the infant's medical record. FOLLOWING THE BIRTH DOSE: The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1-2 months. The final dose should be administered at age ≥24 weeks. It is permissible to administer 4 doses of HepB (e.g., when combination vaccines are administered after the birth dose); however, if monovalent HepB is used, a dose at age 4 months is not needed. Infants born to HBsAg-positive mothers should be tested for HBsAq and antibody to HBsAq after completion of the HepB series at age 9–18 months (generally at the next wellchild visit after completion of the vaccine series)
- 2. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at age 15–18 months. The final dose in the series should be administered at age ≥4 years.

Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap – adolescent preparation) is recommended at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a Td booster dose. Adolescents aged 13–18 years who missed the age 11–12-year Td/Tdap booster dose should also receive a single dose of Tdap if they have completed the recommended childhood DTP/DTaP vaccination series. Subsequent **tetanus and diphtheria toxoids (Td)** are recommended every 10 years.

- 3. Haemophilus influenzae type b conjugate vaccine (Hib).

 Three Hib conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB® or COMVAX® [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required. DTaP/Hib combination products should not be used for primary immunization in infants at ages 2, 4 or 6 months but can be used as boosters after any Hib vaccine. The final dose in the series should be administered at age ≥12 months.
- **4. Measles, mumps, and rubella vaccine (MMR).** The second dose of MMR is recommended routinely at age 4–6 years but may be administered during any visit, provided at least 4 weeks have elapsed since the first dose and both doses are administered beginning at or after age 12 months. Children who have not previously received the second dose should complete the schedule by age 11–12 years.
- 5. Varicella vaccine. Varicella vaccine is recommended at any visit at or after age 12 months for susceptible children (i.e., those who lack a reliable history of chickenpox). Susceptible persons aged ≥13 years should receive 2 doses administered at least 4 weeks apart.
- 6. Meningococcal vaccine (MCV4). Meningococcal conjugate vaccine (MCV4) should be given to all children at the 11–12-year-old visit as well as to unvaccinated adolescents at high school entry (aged 15 years). Other adolescents who wish to decrease their risk for meningococcal disease may also be vaccinated. All college freshmen living in dormitories should also be vaccinated, preferably with MCV4, although meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative. Vaccination against invasive meningococcal disease is recommended for children and adolescents aged ≥2 years with terminal complement deficiencies or anatomic or functional asplenia and for certain other high-risk groups (see MMWR 2005;54 [RR-7]:1-21); use MPSV4 for children aged 2–10 years and MCV4 for older children, although MPSV4 is an acceptable alternative.

- 7. Pneumococcal vaccine. The heptavalent pneumococcal conjugate vaccine (PCV) is recommended for all children aged 2–23 months and for certain children aged 24–59 months. The final dose in the series should be administered at age ≥12 months. Pneumococcal polysaccharide vaccine (PPV) is recommended in addition to PCV for certain high-risk groups. See MMWR 2000; 49(RR-9):1-35.
- 8. Influenza vaccine. Influenza vaccine is recommended annually for children aged ≥6 months with certain risk factors (including, but not limited to, asthma, cardiac disease, sickle cell disease, human immunodeficiency virus [HIV], diabetes, and conditions that can compromise respiratory function or handling of respiratory secretions or that can increase the risk for aspiration), healthcare workers, and other persons (including household members) in close contact with persons in groups at high risk (see MMWR 2005;54[RR-8]:1-55). In addition, healthy children aged 6-23 months and close contacts of healthy children aged 0-5 months are recommended to receive influenza vaccine because children in this age group are at substantially increased risk for influenza-related hospitalizations. For healthy persons aged 5-49 years, the intranasally administered, live, attenuated influenza vaccine (LAIV) is an acceptable alternative to the intramuscular trivalent inactivated influenza vaccine (TIV). See MMWR 2005;54(RR-8):1-55. Children receiving TIV should be administered a dosage appropriate for their age (0.25 mL if aged 6–35 months or 0.5 mL if aged ≥3 years). Children aged ≤8 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by at least 4 weeks for TIV and at least 6 weeks for LAIV).
- 9. Hepatitis A vaccine (HepA). HepA is recommended for all children at 1 year of age (i.e., 12–23 months). The 2 doses in the series should be administered at least 6 months apart. States, counties, and communities with existing HepA vaccination programs for children 2–18 years of age are encouraged to maintain these programs. In these areas, new efforts focused on routine vaccination of 1-year-old children should enhance, not replace, ongoing programs directed at a broader population of children. HepA is also recommended for certain high-risk groups (see MMWR 1999; 48[RR-12]1-37).

CHILD AND ADOLESCENT CATCH-UP SCHEDULE FOOTNOTES

- DTaP. The fifth dose is not necessary if the fourth dose was administered after the fourth birthday.
- 2. IPV. For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age ≥4 years. If both OPV and IPV were administered as part of a series, a total of 4 doses should be given, regardless of the child's current age.
- **3. HepB.** Administer the 3-dose series to all children and adolescents <19 years of age if they were not previously vaccinated.
- **4. MMR.** The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
- Hib. Vaccine is not generally recommended for children aged ≥5 years.
- 6. Hib. If current age <12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or COMVAX® [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.
- PCV. Vaccine is not generally recommended for children aged ≥5 years.
- **8. Td.** Adolescent tetanus, diphtheria, and pertussis vaccine (Tdap) may be substituted for any dose in a primary catch-up series or as a booster if age appropriate for Tdap. A five-year interval from the last Td dose is encouraged when Tdap is used as a booster dose. See ACIP recommendations for further information.
- IPV. Vaccine is not generally recommended for persons aged ≥18 years.
- **10. Varicella.** Administer the 2-dose series to all susceptible adolescents aged ≥13 years.

ADULT SCHEDULE FOOTNOTES

- 1. Tetanus and Diphtheria (Td) vaccination. Adults with uncertain histories of a complete primary vaccination series with diphtheria and tetanus toxoid-containing vaccines should receive a primary series using combined Td toxoid. A primary series for adults is 3 doses; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. Administer 1 dose if the person received the primary series and if the last vaccination was received >10 years previously. Consult ACIP statement for recommendations for administering Td as prophylaxis in wound management (www.cdc.gov/mmwr/preview/mmwrhtml/00041645. htm). The American College of Physicians Task Force on Adult Immunization supports a second option for Td use in adults: a single Td booster at age 50 years for persons who have completed the full pediatric series, including the teenage/young adult booster. A newly licensed tetanus-diphtheria-acellular pertussis vaccine is available for adults. ACIP recommendations for its use will be published.
- 2. Measles, Mumps, Rubella (MMR) vaccination. Measles component: Adults born before 1957 can be considered immune to measles. Adults born during or after 1957 should receive >1 dose of MMR unless they have a medical contraindication, documentation of >1 dose, history of measles based on healthcare provider diagnosis, or laboratory evidence of immunity. A second dose of MMR is recommended for adults who 1) were recently exposed to measles or in an outbreak setting, 2) were previously vaccinated with killed measles vaccine, 3) were vaccinated with an unknown type of measles vaccine during 1963–1967, 4) are students in postsecondary educational institutions, 5) work in a healthcare facility, or 6) plan to travel internationally. Withhold MMR or other measles-containing vaccines from HIV-infected persons with severe immunosuppression. *Mumps component:* 1 dose of MMR vaccine should be adequate for protection for those born during or after 1957 who lack a history of mumps based on healthcare provider diagnosis or who lack laboratory evidence of immunity. Rubella component: Administer 1 dose of MMR vaccine to women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of child-bearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Do not vaccinate women who are pregnant or might become pregnant within 4 weeks of receiving the vaccine. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the healthcare facility.
- **3. Varicella vaccination.** Varicella vaccination is recommended for all adults without evidence of immunity to varicella. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (healthcare workers and family contacts of immunocompromised persons) or 2) are at high risk for exposure or transmission (e.g., teachers of young children; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers). Evidence of immunity to varicella in adults includes any of the following: 1) documented age-appropriate varicella vaccination (i.é., receipt of 1 dose before age 13 years or receipt of 2 doses [administered at least 4 weeks apart] after age 13 years); 2) born in the United States before 1966; 3) history of varicella disease based on healthcare provider diagnosis or self- or parental-report of typical varicella disease for non-U.S.-born persons born before 1966 and all persons born during 1966–1997 (for a patient reporting a history of an atypical, mild case, healthcare providers should seek either an epidemiologic link with a typical varicella case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on healthcare provider diagnosis; or 5) laboratory evidence of immunity. Do not vaccinate women who are pregnant or might become pregnant within 4 weeks of receiving the vaccine. Assess pregnant women for evidence of varicella immunity. Women who do not have evidence of immunity should receive dose 1 of varicella vaccine upon completion or termination of pregnancy and before discharge from the healthcare facility. Dose 2 should be given 4–8 weeks after dose 1.
- 4. Influenza vaccination. Medical indications: Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by HIV); any condition (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder) that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration; and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia. Occupational indications: Healthcare workers and employees of long-term care and assisted living facilities. Other indications: residents of nursing homes and other long-term care and assisted living facilities; persons likely to transmit influenza to persons at high risk (i.e., in-home household

- contacts and caregivers of children birth through 23 months of age, or persons of all ages with high-risk conditions); and anyone who wishes to be vaccinated. For healthy nonpregnant persons aged 5–49 years without high-risk conditions who are not contacts of severely immunocompromised persons in special care units, intranasally administered influenza vaccine (FluMist®) may be administered in lieu of inactivated vaccine.
- 5. Pneumococcal polysaccharide vaccination. Medical indications: Chronic disorders of the pulmonary system (excluding asthma); cardiovascular diseases; diabetes mellitus; chronic liver diseases, including liver disease as a result of alcohol abuse (e.g.,cirrhosis); chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection [vaccinate as close to diagnosis as possible when CD4 cell counts are highest], leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, organ or bone marrow transplantation); chemotherapy with alkylating agents, antimetabolites, or high-dose, long-term corticosteroids; and cochlear implants. Other indications: Alaska Natives and certain American Indian populations; residents of nursing homes and other long-term care facilities.
- **6. Revaccination with pneumococcal polysaccharide vaccine.** One-time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, organ or bone marrow transplantation); or chemotherapy with alkylating agents, antimetabolites, or high-dose, long-term corticosteroids. For persons aged >65 years, one-time revaccination if they were vaccinated >5 years previously and were aged <65 years at the time of primary vaccination.
- 7. Hepatitis A vaccination. Medical indications: Persons with clotting factor disorders or chronic liver disease. Behavioral indications: Men who have sex with men or users of illegal drugs. Occupational indications: Persons working with hepatitis A virus (HAV)-infected primates or with HAV in a research laboratory setting. Other indications: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (for list of countries, visit www.cdc.gov/travel/diseases.htm#hepa) as well as any person wishing to obtain immunity. Current vaccines should be given in a 2-dose series at either 0 and 6–12 months, or 0 and 6–18 months. If the combined hepatitis A and hepatitis B vaccine is used, administer 3 doses at 0, 1, and 6 months.
- 8. Hepatitis B vaccination. Medical indications: Hemodialysis patients (use special formulation [40 μg/mL] or two 20-μg/mL doses) or patients who receive clotting factor concentrates. Occupational indications: Healthcare workers and public-safety workers who have exposure to blood in the workplace; and persons in training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions. Behavioral indications: injection-drug users; persons with more than one sex partner in the previous 6 months; persons with a recently acquired sexually transmitted disease (STD); and men who have sex with men. Other indications: household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff of institutions for the developmentally disabled; all clients of STD clinics; inmates of correctional facilities; or international travelers who will be in countries with high or intermediate prevalence of chronic HBV infection for >6 months (for list of countries, visit www.cdc.qov/travel/diseases.htm#hepa).
- 9. Meningococcal vaccination. Medical indications: Adults with anatomic or functional asplenia, or terminal complement component deficiencies. Other indications: first-year college students living in dormitories; microbiologists who are routinely exposed to isolates of Neisseria meningitidis; military recruits; and persons who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [Dec-June]), particularly if contact with the local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Meningococcal conjugate vaccine is preferred for adults meeting any of the above indications who are aged <55 years, although meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative. Revaccination after 5 years may be indicated for adults previously vaccinated with MPSV4 who remain at high risk for infection (e.g., persons residing in areas in which disease is epidemic).</p>
- 10. Selected conditions for which Haemophilus influenzae type b (Hib) vaccine may be used. Haemophilus influenzae type b conjugate vaccines are licensed for children aged 6 weeks—71 months. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults with the chronic conditions associated with an increased risk for Hib disease. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection, or have had splenectomies; administering vaccine to these patients is not contraindicated.

DTP diphtheria/tetanus/pertussis NIIH National Immunization **GLOSSARY OF** vaccine Information Hotline **ETA Enhanced Technical Assistance** NIIW National Infant Immunization Project Week EIS **Epidemic Intelligence Service** NIP **CDC National Immunization Program ACRONYMS AND FDA** Food and Drug Administration NIS **National Immunization Survey GAO** Government Accountability **NVAC** National Vaccine Advisory Office Committee **GAVI** Global Alliance for Vaccines and **NVPO** National Vaccine Program Office Immunization **ABBREVIATIONS** Global Immunization Vision and **GIVS** NVSN New Vaccine Surveillance **Strategies** Network **HBV** hepatitis B vaccine **OPER** Office of PReparedness and Emergency Response hepatitis A vaccine **HepA AAFP** American Academy of Family **OPV** oral polio vaccine HepB hepatitis B vaccine **Physicians PAHO** Pan American Health **AARP** (formerly American Association of **HHS** Department of Health and Organization Retired Persons) Human Services PCV, PCV-7 AAP American Academy of Pediatrics Hib Haemophilus influenzae type b pneumococcal conjugate vaccine conjugate vaccine Adult Clinic Assessment Software **ACASA** PHII **Public Health Informatics** IAP **Application** Immunization Action Plan Institute IIS immunization information Advisory Committee on **ACIP PPV** pneumococcal polysaccharide Immunization Practices system (registry) vaccine **ACP** American College of Physicians IND investigational new drug **PSA** public service announcement **ACPE** Advisory Committee of Polio **IOM** Institute of Medicine **SBIR** small business innovation Eradication (WHO) **IPV** inactivated poliovirus vaccine research Academy for Educational AED **IRAR** Immunization Registry Annual SIA Supplemental Immunization Development Report Activities **AFIX** Assessment, Feedback, **IRB** institutional review board **STOP** Stop Transmission of Polio Incentives, Exchange: a quality **IRSB** Immunization Registry Support Td tetanus-diphtheria vaccine improvement immunization Branch coverage strategy tetanus and diphtheria toxoids **Tdap** Immunization Services Division ISD Association of Immunization and acellular pertussis vaccine AIM Managers ISO Immunization Safety Office TIV trivalent influenza vaccine **AIRA** American Immunization Registry **KAB** knowledge, attitudes, and beliefs TTY tele-typewriter Association **LAIV** live attenuated influenza vaccine U.S. **United States ANR** audio news release **MCV** measles-containing vaccine **UNICEF** United Nations Children's Fund **AMA** American Medical Association meningococcal conjugate vaccine MCV4 USDA U.S. Department of Agriculture **APhA** American Pharmacists Association (quadrivalent) **USPHS** U.S. Public Health Service **ASTHO** Association of State and measles/mumps/rubella vaccine **MMR VAERS** Vaccine Adverse Event Reporting Territorial Health Officials MPSV4 meningococcal polysaccharide System Behavioral Risk Factor **BRFSS** vaccine (quadrivalent) **VARP** Vaccine Acceptance and Risk Surveillance System **NACCHO** Perception **CASA** Clinic Assessment Software National Association of Country VAU vaccine analytic unit **Application** and City Health Officials **VAXDEV** Vaccine Technology Development **CDC** Centers for Disease Control and **NBCH** National Business Coalition on Prevention Health **VFC** Vaccines for Children Program **CISA** Clinical Immunization Safety **NCID** National Center for Infectious VIS Vaccine Information Statement Assessment Network Diseases VISI Vaccine Identification Standards Center for Medicare and **CMS NCHS** National Center for Health Initiative **Medicaid Services Statistics VMBIP** Vaccine Management Business **CoCASA** Comprehensive Clinic NCHSTP National Center for HIV, STD and Improvement Project Assessment Software Application TB Prevention **VSD** Vaccine Safety Datalink **CRS** congenital rubella syndrome **NFID** National Foundation for **NVPO** National Vaccine Program Office Infectious Diseases DT diphtheria/tetanus vaccine **WHO** World Health Organization **NID** National Immunization Days **DTaP** diphtheria/tetanus/acellular WIC Women, Infants, and Children

NIH

National Institutes of Health

pertussis vaccine

Diphtheria

This serious disease is caused by bacteria that produce a poison or toxin. Diphtheria can cause blockage of the airway, making it impossible to breathe. It can also cause heart problems and paralysis of the muscles needed for swallowing.

Hib Disease

Haemophilus influenzae type b (Hib) bacteria cause meningitis. Hib can also cause pneumonia and infection of the blood, joints, bones, throat, and heart covering. The disease is very serious for children younger than age 5, especially infants. In the prevaccine era, about 3%–8% of Hib meningitis cases were fatal and, of those children who survived, 15%–30% suffered neurologic damage.

Hepatitis A

Hepatitis A is a liver disease. Older persons are more likely to have symptoms, such as fever, tiredness, loss of appetite, nausea, abdominal discomfort, dark urine, and jaundice (yellowing of the skin and eyes) than children. Hepatitis A virus is spread from person to person by putting something in the mouth that has been contaminated with the virus. This type of transmission is called "fecal-oral." For this reason, the virus is more easily spread in areas where there are poor sanitary conditions or where good personal hygiene is not observed.

Hepatitis B

Hepatitis B is an infection of the liver caused by a virus. It spreads through contact with blood or other body fluids due to sexual contact or sharing of personal items such as needles for injecting drugs, razors, toothbrushes, or eating utensils. Hepatitis B causes a flu-like illness with loss of appetite, nausea, vomiting, rashes, joint pain, and jaundice. An infected pregnant woman can expose her newborn to this virus during birth. The virus stays in the liver of some people for the rest of their lives and can result in severe liver diseases or cancer.

Influenza (flu)

Influenza is a highly contagious viral infection of the nose, throat, and lungs. It is one of the most severe illnesses of the winter season and spreads easily when an infected person coughs or sneezes. Influenza may lead to hospitalization or even death, especially among the elderly. Typical symptoms include an abrupt onset of high fever, chills, a dry cough, headache, runny nose, sore throat, and muscle and joint pain. Extreme fatigue can last from several days to weeks.

Measles

The measles virus is spread very easily. Just being in the same room with a person with measles is enough to catch the disease. Symptoms include a rash, fever, cough, and watery eyes. Measles can also cause pneumonia, seizures, brain damage, or death. Of every 1,000 children who get measles, 1 or 2 will die from the disease.

Meningococcal Disease

Caused by a bacteria, meningococcal disease is a leading cause of bacterial meningitis (an infection of fluid surrounding the brain and the spinal cord) in children. Meningococcal disease also causes blood infections, which can be treated with antibiotics; still

about one of every ten people who get the disease dies from it. Survivors may lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizures or strokes. The disease is most common in infants under 1 year of age and people with certain medical conditions. College freshmen living in dorms have an increased risk of getting meningococcal disease.

Mumps

The mumps virus causes fever, headaches, and swollen salivary glands under the jaw. Children who get mumps may develop a mild meningitis (inflammation of the covering of the brain and spinal cord) and sometimes encephalitis (inflammation of the brain). Mumps can also result in permanent hearing loss.

Pertussis (whooping cough)

Pertussis is caused by bacteria. It can cause spells of violent coughing and choking, making it hard to breathe, drink, or eat. The cough can last for weeks. Pertussis is most serious for babies, who can get pneumonia, have seizures, become brain damaged, or even die. About two-thirds of children under 1 year of age who get pertussis must be hospitalized.

Pneumococcal Disease

Pneumococcal disease is a bacterial infection that invades the lungs, causing the most common kind of bacterial pneumonia, which can invade both the bloodstream (bacteremia) and the brain (meningitis). Symptoms include high fever, cough with chest pain and mucus, shaking chills, breathlessness, and chest pain that increases with breathing. Older adults often experience changes in level of consciousness or confusion.

Polio

Polio is caused by a virus that is spread by contact with the feces (bowel movement) of an infected person. Symptoms can include sudden fever, sore throat, headache, muscle weakness, and pain. Polio can cause paralysis and death.

Rubella (German measles)

The rubella virus usually causes a mild sickness with fever, swollen glands, and a rash that lasts about 3 days. But if a pregnant woman gets rubella, she can lose her unborn baby, or the baby can be born blind, deaf, mentally retarded, or with heart defects or other serious problems.

Tetanus (lockjaw)

Tetanus is caused by a toxin or poison produced by a bacteria that enters the body through a cut or wound. Tetanus causes serious, painful spasms and stiffness of all muscles in the body and can lead to "locking" of the jaw so a person cannot open his or her mouth, swallow, or breathe. Three of 10 people who get tetanus die from the disease.

Varicella (chickenpox)

The varicella virus usually causes a rash, itching, tiredness, and fever. It can sometimes lead to severe skin infections, pneumonia, brain infection, or death. Complications occur most often in very young children, adults, or people with damaged immune systems.

VACCINE-PREVENTABLE

DISEASE

DEFINITIONS

CONTACT INFORMATION

NATIONAL IMMUNIZATION PROGRAM

PROGRAM CONTACT

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CDC-INFO CONTACT CENTER

800-CDC-INFO (232-4636) cdcinfo@cdc.gov TTY: 888-232-6348 In English, En Español – 24/7

IMPORTANT WEBSITES

Centers for Disease Control and Prevention www.cdc.gov

National Immunization Program www.cdc.gov/nip





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We're already making a huge difference, but there's so much more we can do during the next few years with the recent licensure of new vaccines and several new vaccines on the horizon. There are also enormous opportunities for improving our adult and adolescent immunization programs, narrowing some of the gaps in the childhood immunization program, and assuring equity throughout the U.S. population. And there are opportunities on the global front, with polio eradication and measles mortality reduction. It's tremendous to think about how much of a difference we can make.

—DR. ANNE SCHUCHAT DIRECTOR, NIP



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